EXHIBIT B

CAUSE NO. 2012-CI-18690

JENNIFER RAMIREZ F/K/A JENNIFER GALINDO, Plaintiff, v. CESAR REYES, M.D., JOHNSON & JOHNSON, AND ETHICON, INC., Defendants.	)	IN THE DISTRICT COURT 438th JUDICIAL DISTRICT BEXAR COUNTY, TEXAS

DEPOSITION OF

JAIME SEPULVEDA, M.D.

DATE: April 8, 2016

TIME: 9:17 a.m. - 5:10 p.m.

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WITNESS:

EXHIBITS

The deposition of JAIME SEPULVEDA, M.D., a witness in the above-entitled and numbered cause, was taken before me, Dorothy Linda Minor, Registered Professional Reporter and Notary Public for the State of Florida at Large, at 200 South Biscayne Boulevard, Suite 4600, in the City of Miami, County of Miami-Dade, State of Florida, on Friday, the 8th day of April, 2016.

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THE VIDEOGRAPHER: We're on the record. The witness is not present. Counsel Tim Goss has requested the video be turned on for objections regarding the video. The time is 9:12 a.m., and the matter is Jennifer Ramirez versus Ethicon, et al. Today's date is April 8, 2016.

MS. GALLAGHER: This is Kat Gallagher on behalf of Johnson & Johnson, and we have a, and Ethicon, and we have a deposition notice for Dr. Sepulveda today that was noticed for stenographic only. Pursuant to Rule 199.2, we object to this going forward by video because under Rule 199.2, at least five days prior to the deposition, the party must serve on the witness and all parties a notice that the deposition will be recorded by other than stenographic means. We did not get five days notice and I object to it going forward by video.

MR. GOSS: And just so I'm clear on your objection, you object to us by recording -- you object to our recording of the deposition, even in the event that we do not intend to use the video of the deposition at any trial in this

cause?

MS. GALLAGHER: Yes, I do, because under the rule it says that notice must be given that the deposition will be recorded by other than stenographic means. It does not say used.

MR. GOSS: And you refuse to let us go forward in the event that we want to record it, video it for our own purposes and for no purpose to be used at trial?

MS. GALLAGHER: Yes.

MR. GOSS: And we've offered you that we would not use it for any purpose at trial and you refuse to proceed forward, even under that condition?

MS. GALLAGHER: Yes.

MR. GOSS: Okay. Just for the record, we will take this to the Court. In the event that the Court determines that we are entitled to video it for our own purposes, then we're going to ask to come down here and take it again. That's all.

THE VIDEOGRAPHER: This is the end of video portion. It's 9:14 a.m.

THE COURT REPORTER: Raise your right hand, please, sir. Do you swear or affirm that

the testimony you are about to give will be the truth, the whole truth and nothing but the truth?

THE WITNESS: I do swear.

THEREUPON,

JAIME SEPULVEDA, M.D.,

having been first duly sworn/affirmed to tell the truth, the whole truth and nothing but the truth, was examined and testified under oath as follows:

DIRECT EXAMINATION

BY MR. FREESE:

Q. Good morning. Good to see you again. I'm going to mark Exhibit 1 to your deposition, which is the notice of your deposition.

(Plaintiff Exhibit No. 1 was marked for identification.)

BY MR. FREESE:

Q. Have you seen that before, sir?

A. Yes, sir.

Q. All right, and you were provided a copy of it before the deposition?

A. Yes.

Q. And you were requested to bring some documents?

A. Yes.

Q. Okay. And did you do so?
A. Yes, I did.
Q. And I'm going to mark Exhibit 2 to your deposition, which is Ethicon's response to the deposition notice.
(Plaintiff Exhibit No. 2 was marked for identification.)
BY MR. FREESE:
Q. Have you seen that before?
A. I see it for the first time now.
Q. Me showing you now, that's the first time you've seen it?
A. Yes, sir.
Q. Okay. You don't know what Ethicon objected to producing and what it didn't object to producing?
A. Yeah, I'm aware that they objected to my 1099s.
Q. Okay, and other than your 1099s, was there anything withheld that we requested to be brought, other than the 1099s?
A. Not that, not that I'm aware.
Q. Okay. So, everything that you have looked at and relied upon is either physically in the room either in paper form or on a thumb drive?

A. I have, I have made an effort to put everything there on the floor and I have my thumb drive.
Q. Okay, my question is, is everything that you have reviewed and relied on in this case either on the thumb drive or on the floor in paper format?
A. Yes.
Q. And the only set of documents that have been withheld are your 1099s?
A. Yes.
MS. GALLAGHER: And, Rich, just to be clear, I don't know if all of the literature is on this thumb drive, but I think all the case-specific materials are on there. I'm just not clear if we loaded up all the literature again.
MR. FREESE: Okay.
BY MR. FREESE:
Q. And, Doctor, we were provided a supplemental reliance list of yours this week. Did you realize that?
A. Yes.
Q. So, let me go ahead, and I'm going to mark what was referenced to us as your reliance list as Exhibit 3, and I'm going to mark as Exhibit 4 your

supplemental reliance list that is printed, it says April 5, 2005, which I guess was three days ago.
(Plaintiff Exhibits No. 3 and 4 were marked for identification.)
A. Yeah.
BY MR. FREESE:
Q. Is that right?
A. That's right.
Q. Okay. And is Exhibit 4 your supplemental reliance list?
A. Yes, this looks like my reliance list and I would say supplemental reliance list.
Q. Okay, and do you know sitting here what was added or subtracted from your supplemental reliance list?
A. This has articles on, on other, other, this has articles on biomechanics, and, as I can see just flipping through these, these pages, it has my, all the things that I relied that I testified on last week.
Q. Okay. Well, what I'm, what I'm trying to find out is, is there a way that I can, without going line by line, figure out what it is you added to your supplemental reliance list on the 5th of April, three days ago?

A. No, I've been giving articles that I come across but I did bring the articles that are not in here.
MS. GALLAGHER: Rich, I might be able to short change this. I think the only thing that was added were additional medical records that didn't make the original list. I don't believe there's any additional articles on there, is my understanding.
MR. FREESE: That's what I'm trying to find out.
BY MR. FREESE:
Q. So, based on what, what Ms. Gallagher said, does that sound accurate to you, Doctor, that the only supplement has been additional records?
A. That sounds accurate.
Q. And in fairness, this reliance list is not prepared by you, is it?
A. No, initially it's given in a packet, although I can tell you that most of these articles I read through them through the years.
Q. I understand. I move to strike that. That's not really my question, Dr. Sepulveda. These reliance lists, Exhibit 3 and Exhibit 4, are prepared by lawyers for Ethicon, not by you, correct?

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A. That is correct.
Q. You didn't sit here at your computer and create 70 or 80 pages of single-spaced reliance materials?
A. I did put together the articles, I did the research for the articles that are included initially on the TVTO summary that is used in this case.
MR. FREESE: Move to strike.
BY MR. FREESE:
Q. Not my question, sir. You didn't sit here and prepare at a computer your reliance materials. That was done by the lawyers, correct?
A. Yes, on the computer was done by them.
Q. And then it's attached to your report, correct?
A. Yes.
Q. Okay. And your testimony is that you think over the years you've seen or read most of the things on your reliance list?
A. I would say all of them.
Q. So you've read all the internal Ethicon documents referenced on your reliance list?
A. I have a binder that has been provided to me with the TVTO company documents.

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Q. Okay, and did you bring it here with you today?
A. Yes, I did.
Q. And do you have a binder of those?
A. Yes.
Q. Do you mind grabbing that?
A. No.
Q. And would you go ahead and describe what's in this binder for me?
A. It's a, it's a group of, it's a mixed group of the history of TVTO, the -- I'm not going to read the whole thing.
Q. That's fine, just a narrative.
A. But, the summaries of how TVTO was developed.
Q. Okay. And, again, these were internal documents that were hand picked by the lawyers for Ethicon, is that correct?
A. They, they were provided to me. I don't know what, what method they used.
Q. Well, the method was, they chose which documents to supply to you, correct?
A. I, I think, I think, yes.
Q. Okay. And is there any specific internal document that you asked them to provide to you?

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A. No.
Q. Okay. So, one hundred percent of the internal documents that you've looked at regarding TVTO or any meshes that you testify about are hand selected and given to you by Ethicon, correct?
A. Yes.
Q. All right, Doctor, we're going to go ahead and mark your copy of the -- this is the report prepared in this case, is that correct?
A. Yes.
Q. All right, I'm going to mark as Exhibit 5 --
MR. JORDAN: Can we mark this and get a copy of this? I think what we would like to do is just mark it so he can have his original back and we can replace the copy with the depo when we get it. I just want it in the record that he brought this and what it is.
MS. GALLAGHER: Yeah, that's fine, it's just because trial is so close we just want to get his materials back to him as fast as we can.
BY MR. FREESE:
Q. So, I'm going to mark as Exhibit 5 the documents that Ethicon's lawyers provided to you of the

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internal records of the company, the binder.
A. I understand.
(Plaintiff Exhibit No. 5 was marked for identification.)
BY MR. FREESE:
Q. Okay. I'll mark as Exhibit 6 your expert opinion in the Jennifer Ramirez case.
(Plaintiff Exhibit No. 6 was marked for identification.)
BY MR. FREESE:
Q. Is that correct?
A. Yes. You mean my marked copy?
Q. Yes, I want to mark your marked copy.
A. Yes.
Q. And these are, the pink stickies are yours?
A. Yes.
Q. In your handwriting?
A. Yes.
Q. And there's highlighting here also, correct?
A. Yes.
Q. Generally, what is it that you highlighted?
A. Anything that I, I anticipate that you

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would ask me about.
Q. Okay. Fair enough. And I'm going to give it back to you, and I may, I may ask to get it back to see what's highlighted and what the notes say when I get to that particular page. Okay?
A. Okay.
Q. Doctor, I'm going to try to do this in just page-flipping order so we can get through this, but am I correct that this expert report is virtually identical to a number of expert reports that you have issued in synthetic mesh litigation lawsuits?
A. They, the general report, yes.
Q. The credentials and qualifications would be virtually identical?
A. Yes.
Q. Okay, and the general opinions that you hold about TVT and TVTO and TVTS are all virtually identical?
A. Yes, sir.
Q. Okay, and then we have some opinions that are specific to Ms. Ramirez's case, correct?
A. Yes.
Q. Okay. Am I correct, like your reliance list, that your expert report is not prepared by you but rather is prepared by the lawyers for Ethicon?

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A. No, that's not correct.
Q. Okay. So, who actually types this report?
A. I, I did.
Q. You typed this 66-page report?
A. I actually did.
Q. Okay, and how long did it take you to type this 66-page report?
A. I'm going to, I'm going to, I misspoke on the, the whole report. The, the part that has to do with the life care plan, I did not type that one.
Q. Okay. So, the life care plan opinion starts at page 63 of your report?
A. Yes, that's correct.
Q. And you did not type that?
A. No, I did not type the comments on the life care plan.
Q. Who prepared your comments on the life care plan?
A. The, the attorney's office.
Q. Okay. Do you know who in the attorney's office?
A. No.
Q. Okay. Did you actually review any underlying records to create the comments in the life

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care plan?
A. If I -- repeat that again, please.
Q. Yes, sir. There's four pages of, of opinions that you have about the life care plan that you say you did not prepare.
A. No, I did not type those, and, and those were prepared by the attorney's office and I reviewed them.
Q. Okay, you reviewed the comments?
A. Yes.
Q. Did you review any of the underlying documents that made up the life care plan?
A. Yes, I reviewed the documents prepared by Mr. Harrell, and I read the deposition of Dr. Elizondo.
Q. All right, and these are -- were there anything other than those two depositions that you read?
A. No.
Q. Did you read the entirety of the depositions?
A. I, yeah, Elizondo, I read the whole thing.
Q. Were there portions selected for you by the lawyers, or did you just, you sat down and read the whole deposition?

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A. No, that one I read the whole, whole deposition.
Q. I can look at your reliance list, but there are a lot of depositions that are listed here. Did you read every one of them?
A. At some point, I have read them, because being this is so long, this is two years, but yes, I have read the depositions, and they don't all come, as you probably would know, they don't come at one time. They come in sequence.
Q. So, over the period of Ms. Ramirez's case, you've read several thousands of pages of deposition testimony to form your opinion, correct?
A. Yes, sir.
Q. And that would include all of her treating physicians?
A. Yes, all the treating physicians that I've been made aware of by the medical records.
Q. Her deposition, correct?
A. Two, both of them.
Q. Three of them. Did you know there were three, three installments of her deposition?
A. No, I read two, two depositions.
Q. Did you know there were three?
A. No.

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Q. Okay. What two versions did you read?
A. I read the first and the second depositions.
Q. Okay.
A. That's the transcript of each one.
Q. You didn't read the third version?
A. No.
Q. So your opinions can't be influenced in any way by what she said in her third deposition, correct?
A. No, I have not read it, I cannot rely on it.
Q. And you don't intend to give any opinions based on anything that was said in her third deposition?
A. I'm not even aware that there was a third deposition, so I definitely could got rely on.
Q. So anything that was said in the third deposition can't form any basis for any opinion you're giving, correct?
A. Unless I read them before trial, and then everybody should be aware if anything changes.
Q. I'm talking about as you sit here today, we've got your report, we've got you here under oath giving your opinions, you can't opine, don't intend to

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opine on anything said in her third deposition?
A. No, I have not read it.
Q. Okay. Now, real quickly, you're the medical director of South Miami Medical Arts Surgery, correct?
A. Yes.
Q. And that's, that's where you work?
A. That's one of the places where I work. That's, that's a surgery center that is a partnership between the surgeons and Baptist Health System.
Q. And what do you do as the medical director?
A. I oversee credentialing, oversee the directory for pharmacy, I oversee any incidents, incident reports, and I, I also prepare for joint commission reviews and AHCA, A-H-C-A, reviews.
Q. It says you are a principal investigator of the Fibroid Registry Research Project. What is that?
A. Yes, that's a registry, it's a research, and, it's a research project, and it was registered and has been closed.
Q. What was it a research project of? And what was the purpose of the project?
A. Well, there's a fibroid center at the

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hospital, and I put together the research, I cooperate with the research instruments, I oversee the research instruments as the principal investigator. That includes IRB submissions and registering in the clinicaltrials.gov site.
Q. But the registry is closed?
A. Yes, when we finish our project, we are required to close that registry or that project on the clinicaltrials.gov.
Q. So you're no longer an investigator for that?
A. No.
Q. I guess we should take that out of your résumé, should we not?
A. You can actually strike it, yeah.
Q. Okay. And it says that, the conference director for the Pelvic Floor Board. What is that?
A. The Pelvic Floor Board is a group of colorectal, radiologists, physical therapists, gastroenterologists, neurologists, urogynecologists, gynecologists, and neurologists and pain management specialists. We all get together every quarter and we present cases, discuss cases and treatment strategies and share knowledge.
Q. Is this national or international, or is

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that just here in Miami?
A. That's a CME activity. It's one-credit CME activity here at Baptist Health.
Q. Okay, that's what I'm getting at, it's a local entity?
A. That's correct.
Q. And you set up the conferences for it?
A. Yes, I'm the conference director.
Q. Okay. Now, you're a member of the American Urologic, Urogynecologic Society, is that right?
A. Yes.
Q. That is an organization made up of doctors who practice urology and gynecology?
A. Yeah, we, AUGS started in the '90s, and it was put together by Dr. Jack Robertson, and he, now it's just the society that represents those with an interest or a board certification in urogynecologic medicine and reconstructive surgery.
Q. That's commonly referred as to AUGS?
A. AUGS.
Q. And am I correct, as long as you're a doctor practicing urology or urogynecology and you submit your application, you can be a member of the organization, correct?

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A. That's correct.
Q. You don't have to take a test to get in there?
A. No.
Q. You don't have to be invited?
A. No.
Q. You're just, I'm a doctor, I do gynecology, I do urology, I would like to be a member, here's my dues, I'm in, correct?
A. Yes.
Q. Okay, and in fact, Ethicon is a member of AUGS, is that correct?
A. I did not know that.
Q. Is me telling you, is that the first time you ever heard it?
A. Yes.
Q. Okay. And then it says that you're a member of the American Urological Association, AUA, is that correct?
A. Yes.
Q. Same thing, that's an organization that you don't have to be invited to, correct?
A. No, that one I was invited.
Q. You don't have to be invited to it, correct?

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A. For me as a gynecologist to be a member, yes.
Q. Generally, anyone who is a practicing urologist who wants to be a member of the AUA can submit an application to be a member, correct?
A. If you are a urologist.
Q. That's my point. And you are.
A. No, I'm a urogynecologist.
Q. I understand, but you practice urology and gynecology, do you not?
A. I practice female pelvic medicine and reconstructive surgery. That's my board certification.
Q. And, so, any doctor who practices in that field can apply, pay a due and be a member of AUA, correct?
A. I think for urologists, they are board certified in urology. I am not sure.
Q. As you sit here today, you didn't have to take a test to be an AUA member, did you?
A. No, for me to be a member, I had to be invited and sponsored by a urologist.
Q. And then you pay your dues and you become a member, correct?
A. Yes.
Q. All right. The IUA, the International

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Urogynecologic Association?
A. Yes.
Q. Is that IUGA?
A. Yes.
Q. Okay. What about that organization, do you have to be invited to that, or can you simply join it?
A. No, you join.
Q. Okay, you pay your dues, submit your application, Dr. Sepulveda, you're a member, correct?
A. Yes.
Q. ICS, International Continence Society, that's also a group, that was founded in England, right?
A. I don't know if it was founded in England. I know it's a great source of information.
Q. And that's simply, I'm Jaime Sepulveda and I want to be a member, here's my money and here's my application, and you're in, correct?
A. Yes.
Q. All right, you were not invited to be a member of ICS?
A. No.
Q. Anybody who is a doctor who pays the dues can be a member of ICS, correct?

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A. Yes.
Q. Does your experience in neuromodulation have anything to do with the opinions you're giving in this case?
A. No, not neuromodulation.
Q. It's in your report, so I just want to make sure, as I go through this, I want to see if it impacts your opinions, and if it doesn't, we won't spend any time on it.
A. No, neuromodulation is used for urge incontinence, but it's not something that I would recommend for Mrs. Ramirez at this time.
Q. And you said that you have a good bit of experience with TVT, TVTO and TVT Secur, correct?
A. Yes.
Q. And you describe it in your report as three generations of TVT products, correct?
A. Yes.
Q. Okay. And all three of those use the same mesh, correct?
A. Yes.
Q. The, the method of implanting is different, correct?
A. Yes.
Q. The length is different?

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A. Yes.
Q. And, but in your mind, those three products represent three different generations of, of the TVT family of products?
A. Yes.
Q. All right. You also implant TVT Abbrevos, do you not?
A. Yes.
Q. Is that part of the third generation, or is it a fourth generation, or where do you put Abbrevo in the hierarchy of --
A. It's probably, we're going to call it fourth generation just by when they came in.
Q. Okay. It was put on the market in 2010 after, after the other three, correct?
A. It might be around that time.
Q. I'm just curious why you didn't put Abbrevo in your report.
A. I don't know, probably just going the Abbrevo in the same, in my mind I think it's the same way as the TVTO.
Q. It's an obturator approach?
A. It's a transobturator approach with midurethral synthetic sling.
Q. And you put a lot of Abbrevos in, don't

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you?
A. Yes.
Q. Okay. You're not putting the Secur in anymore, correct?
A. I don't have it.
Q. Okay. Because it was taken off the market, wasn't it?
A. I don't have it, I just don't have it available.
Q. I know you don't, and the reason you don't have it is because it's not made anymore, is it?
A. It's not made anymore.
Q. Because Ethicon took it off the market, correct?
MS. GALLAGHER: Object to form.
A. Yeah, they decommercialized it.
BY MR. FREESE:
Q. Well, decommercialization, is that what you mean, they decommercialized it?
A. Yeah, that's the term that has been used.
Q. That's not even a word, is it?
A. I don't know.
Q. I mean, I'm not trying to be funny. Decommercialization is not even a word, is it, Doctor?
A. I don't know.

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Q. Did you ever look up decommercialization in the dictionary?
A. Never looked at it.
Q. It doesn't exist, I'll invite you to look it up. What you mean by decommercialization is, TVT Secur was taken off the market by Ethicon, was it not?
MS. GALLAGHER: Object to form.
A. What I consider is that they don't sell it anymore.
BY MR. FREESE:
Q. That's right, because they don't make it anymore and they don't market it anymore, correct?
A. They don't sell it, they don't market it anymore.
Q. And why don't they market it anymore?
MS. GALLAGHER: Object to form.
A. It was a decision that came on, on a letter that they explained that, because there were other, other -- there was other methodology that was going to be used for submission to the FDA. They, they could not make it anymore. They decided not to make it anymore.
BY MR. FREESE:
Q. And they decided not to make it anymore because the FDA told them that the FDA was not

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satisfied with the safety of the TVT Secur, correct?
MS. GALLAGHER: Object to form.
A. I think that it was -- I don't know if it was about safety, I think it was more about getting post-market surveillance.
BY MR. FREESE:
Q. You know that the FDA sent a letter to Ethicon saying that it was not satisfied that the safety of the TVT Secur was established and therefore the company was going to be required to do 522 studies in order to keep marketing the product, and rather than do the studies to prove the safety, the company took the product off the market, correct?
MS. GALLAGHER: Object to form.
A. I know that there was a request for a 522. I cannot tell you that it was because of safety.
BY MR. FREESE:
Q. Well, what else does the FDA regulate products for other than safety?
A. They, they, they do safety, efficacy and quality of products.
Q. Okay, and as you sit here today, do you know of anybody disputing the quality of the TVT Secur?
A. No.
Q. Do you know of anybody disputing the

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efficacy of the TVT Secur?
A. No.
Q. You do know that they were disputing the safety of the TVT Secur, correct?
A. I do not know that.
Q. As you sit here today, you have no idea why the company took the TVT Secur off the market?
A. I, I don't have a clear idea why.
Q. And does the 522 order relate to the safety of a product or the efficacy of a product?
A. I think it has to do with post-market surveillance.
Q. And is post-market surveillance focused on safety or efficacy?
MS. GALLAGHER: Object to form.
A. I already say I don't know if it's about safety. I know a post-market surveillance is a lot more involved than just safety.
BY MR. FREESE:
Q. You think post-market surveillance has to do with the efficacy of a product?
A. I believe it does.
Q. And you think the criticism that the FDA had in the post-market surveillance of TVT Secur was because of the efficacy of the product?

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MS. GALLAGHER: Object to the form.
A. There was a, there was a, now that you mentioned it -- can I refer to one of my documents? Because it's in my, it's in one of the documents that I brought.
BY MR. FREESE:
Q. Sure. Do you need to look at a document to answer my question?
A. Well, we have been talking about the same question already in four separate instances, and if I'm going to answer your question accurately I would like to refer to my document.
Q. You mean four separate depositions you've given?
A. I don't understand your question.
Q. I don't understand your answer. You said we've been talking about it in four separate instances. What did you mean, sir?
A. Well, you asked me already about safety and that the 522 has to do with safety, and before I give you an answer I want to make sure that I give you an accurate answer, and I want to see the document.
Q. Go ahead.
A. I'm looking at the white paper from the FDA.

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Q. All right. Look at page 4, if you don't mind, sir.
MS. GALLAGHER: What document are you looking at?
MR. FREESE: I'm looking at this document.
BY MR. FREESE:
Q. Is that the same one you're looking at?
A. Yes, this is the FDA Executive Summary for surgical mesh for treatment of women with pelvic organ prolapse and stress urinary incontinence.
Q. Look at page 4, section 2.3, regarding 522 post-market surveillance studies.
A. I'm looking at page 4.
Q. Okay. Is this what you needed to look at to answer the question?
A. No, I was looking at the decision of the committee on the post-market option. Yes. What would you like me to read?
Q. My question is, the post-market surveillance studies that the FDA had required Ethicon to conduct related to the serious adverse health consequences that may be caused by a failure of the product, correct?
A. About the, about the efficacy and safety

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and quality.
Q. About the, the 522 allows the FDA to order the study where the failure of the device was reasonably likely to have a serious adverse health consequence. Correct?
A. Are you reading on the pelvic organ prolapse section?
Q. I'm reading page 4 on 522 studies.
A. Yes. Well, I'm going to read on page 47, which is a more specific question about TVT Secur.
Q. Okay. Go ahead.
A. The panel will be asked to consider whether 522 studies are needed for cleared mini-slings, all cleared surgical mesh indicated for stress urinary incontinence, not needed for these devices. If the panel believes 522 are needed for all or just a subset of these products, the panel will be asked to discuss the type clinical study that should be required with consideration to patient selection, controls, randomizations, outcome measures, concomitant surgeries, follow-up duration, etcetera.
Q. Okay, and you agree with the FDA statements in the summary about the TVT Secur?
A. I, I agree that they are in all the power to choose whatever method they decide to choose.

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Q. I understand, but do you agree with the comments that they made about the safety of the TVT Secur?

A. I don't think that TVT Secur is an unsafe procedure; therefore, I see no reason to go beyond what was already being done. Now, I do understand that will benefit from surveillance in any product in which there are being reports of any, any type of incident.

Q. Rather than do the post-market 522 studies, the company, rather than approve the safety of the product through those post-market studies, chose to take it off the market, correct?

MS. GALLAGHER: Object to form.

A. The safety of the product has been, is already being examined independently from the FDA. There have been through, there have been studies through separate, separate studies and trials. What they, the FDA decided was to do 522 because that's a mechanism that they have in place.

BY MR. FREESE:

Q. All you're saying is the FDA did what they have the right to do. I'm asking you if you agreed with what they did.

MS. GALLAGHER: Object to form.

A. I, I disagree with the methodology of the

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FDA which has proven to this time to be inadequate to regulate and innovate at the same time. This type of criminology of 522s or 510(k)s have been in place for a long period of time, and it's, there's a consensus that this need to be reviewed. Now, at the time that this was decided, all this consensus came through, the 522 was the mechanism in place.

BY MR. FREESE:

Q. Right. You read the executive summary, did you not?

A. I did.

Q. And you read it in forming your opinions in this case?

A. Yes.

Q. And you agree with all the, the FDA statements in the summary?

A. No, I don't agree with all of them and I don't disagree with all of them.

Q. You disagree with some and agree with others?

A. There are parts in which I have no opinion.

Q. I guess it would be fair to say you don't think that FDA statements are always well founded in science, correct?

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A. That's correct. I think it's based on the best science that they consider, but there's a bias on the methodology to come to their conclusions and recommendations.

Q. Can you describe to me, Dr. Sepulveda, what bias the FDA has?

A. Well, it's a very small group, and, and it's, it's a group, I believe it's 12, 12 individuals, and the methodology used on the statistical analysis was not, was not fully, fully completed, fully disclosed, I should have said, fully disclosed. Also, the way the complaint were examined, from the MAUDE, from the MAUDE database was put through an Excel program, it was required to be placed on an Excel program to trim down the repeated complaints. So, the MAUDE database was used but there's, within itself has its own, its own limitations.

I'm going to, I'm going to, I'm going to read the limitations of the MAUDE data analysis, which is on the FDA reports, in which it says the reports were unduplicated using Excel on duplication function, not by reviewing the individual reports. A few unduplicated reports might still exist in the data. This auto function does not exemplify reports that have different numbers but are related to the same events.

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If one event has two reports, one from the manufacturer and one from voluntary reporter, but they are not linked in the MAUDE database as one event, they will not be taped by auto function as one event.

So, that tells you the accuracy of the data that was obtained on, on, on this recommendations.

In addition, even though the result of data mining were refined multiple times, it is still possible that a few reports are placed in the wrong group and in the wrong adverse event group.

I just read the way, the way the FDA itself, the group, says that there's a limitation about data analysis. That is biased.

Q. And, therefore, you think that conclusions that the FDA reached are unreliable?

A. I think that they were biased.

Q. Okay, and therefore, if they're biased, they're unreliable, correct?

A. They're not accurate.

Q. And if they're not accurate, they're not reliable?

A. If you want to equate accurate with reliable, yes.

Q. I just want to see if you agree with me.

A. Well, reliable is more, is no more the

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word of accuracy. Reliable is how good the methodology and conclusions are.
Q. And if methodology is biased, that would lead to unreliable results, correct?
A. I think that most people would judge it as unreliable.
Q. I mean, you understand evidence-based medicine, correct?
A. Yes.
Q. If you're practicing evidence-based medicine, you don't want unreliable data to rely on, do you?
A. No, I want the most accurate data that I can obtain.
Q. And, therefore, bias would be a type of unreliable data, correct?
MS. GALLAGHER: Object to form.
A. There's no cohort methodology, there's no randomization, there's no actual analysis conducted on this. The whole, the whole concept of evaluating either efficacy or quality in general, in general, I'm talking in general now, in general, we already mentioned for mini-slings and now we're talking in general, in general is that the amount of database is not accurate, and if it's not accurate, you cannot

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consider reliable.
BY MR. FREESE:
Q. Thank you. And, Dr. Sepulveda, do you think that you are more qualified to assess the safety and efficacy of mesh products than the FDA?
A. I, I cannot substitute a panel of 12 people. I cannot substitute a cohort study. It's not that I'm more qualified. I, I am the receiving end of it. So, I can tell you in this receiving end how I can use it.
Q. Okay, that's not really my question. My question is, do you think that you're more qualified to assess the safety and efficacy of mesh products than the FDA, yes or no?
MS. GALLAGHER: Object to form.
A. I have, I have the experience with working with mesh, I have the knowledge on the biomechanics of mesh, I have the knowledge on the conditions that require the mesh, and I have 25 years doing surgery, but that still leaves me in the receiving end of it. Am I more qualified than the FDA? I think I am as qualified as anyone that was in that panel or that spoke to the FDA.
BY MR. FREESE:
Q. Now, Doctor, you said in your report that

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you have had over 500 surgeons visit your operating room to watch you place slings, correct?
A. Yes.
Q. How many of those were sponsored by Ethicon?
A. I think that the majority of them.
Q. Well, I mean, like 99 percent or 51 percent?
A. I never run a percentage of it, but I have had, I have had surgeons that come without, without Ethicon. The majority could be more than 50 percent. This, this pelvic floor, pelvic floor surgery and the specific procedures did not start with mesh. We were doing this procedures and we were using different procedures even before mesh. In the same way that I visited many surgeons, even before there was mesh, they also visited me.
Q. Okay. Well, did you place any midurethral slings that weren't synthetic? Midurethral slings by definition are synthetic slings, are they not?
A. Yes, there's no data that indicates that midurethral slings should be anything but synthetic.
Q. I understand. My question, Doctor, I'm asking you about your report, and you said 500 doctors

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have come to my operating room to watch Dr. Sepulveda put in midurethral slings. You did say that, did you not?
A. No, not just midurethral slings.
Q. Well, let's look at your report, sir. Page 2, quote, "I have had over 500 physicians visit my operating room to watch me place midurethral slings." Did you write that?
A. Midurethral slings along with other procedures.
Q. That's not what your report says, is it, Doctor? Is it?
A. No, it's not what my report says.
Q. What your report says is 500 doctors have come to your OR to watch you place midurethral slings, correct?
A. Yes.
Q. That means 100 percent of those 500 doctors would be watching you place a synthetic midurethral sling, correct?
A. Yes, they have watched me place a midurethral sling, correct.
Q. Okay. How many of these 500 doctors that came to watch you put synthetic slings in were sponsored by Ethicon?

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A. The majority.
Q. Is it closer to 500 or is it closer to 250?
A. It might be a number between the both of them, but I can not give you an accurate number because I never recorded it.
Q. Okay. How do you know it's 500 then, if you never recorded it?
A. Because that's the number, that's the number that -- it may have been a thousand.
Q. Okay.
A. It may have been a thousand, may have been 400, but I can tell you that at least 500, because in 25 years doing surgery and you have individuals coming to watch you.
Q. Did you just pick the 500 out of the air?
A. Yeah, that's the safest number I could pick. I could have picked a larger number, though.
Q. Okay. And how many years have you been doing midurethral slings?
A. It's since TVT came out.
Q. 1998?
A. Yes.
Q. All this 25-year stuff you're talking about has nothing to do with when you're talking about

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midurethral slings, does it?
A. No, we, we actually dissected the urethra, so that -- okay, yes --
Q. Just answer my question, Doctor. All of this talk about I've been doing this 25 years has no application to midurethral slings, does it?
A. Yes, I have not placed midurethral slings for 25 years.
Q. Because they've only been on the market for 18 years, correct?
A. That is correct.
Q. Okay, and no 500 doctors have seen you place a midurethral sling?
A. It might be 500, it might be more.
Q. And who comes and sees you place midurethral slings in the OR other than people sponsored by Ethicon?
A. I have, I have colleagues that come in, I do Miami, they come to Miami, and they say I'm going to go and see Jaime do surgery. The first one that comes to mind is the chairman, the director of gynecologic surgery at the University of Puerto Rico. Another colleague in Savannah. Another colleagues also from Puerto Rico that is doing academics. I have had fellows, I have had residents from other institutions

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that come and watch me place it. That's essentially. I could go on with a list, but I don't keep a registry.
Q. All right. And when, when Ethicon sponsors these doctors to come watch you place slings, is Ethicon paying you to do that?
A. Yes, they, they, they were, those were mostly activities in which I demonstrated how to place product, and some patients with product also had a midurethral sling.
Q. Okay, but when these doctors that are sponsored by Ethicon are coming in, you're being paid by Ethicon to let them come into your OR to watch you do surgeries?
A. Yeah, they compensate me for my time before I do my surgery. When I'm doing my surgery, I'm being compensated for my surgery.
Q. Now, you say that you, you've used laser-cut mesh and mechanically-cut mesh, correct?
A. Yes.
Q. If I'm holding a TVTO box, for example, all right, how can I tell if it's a mesh, if the mesh is laser cut or mechanically cut?
A. I don't know by looking at the box because when I'm scrubbed, I'm not looking at a box but I look at the product.

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Q. Okay. So, you're an expert, you hold yourself out as an expert in TVTO, correct?
A. Right.
Q. And we can agree that if you're looking at the box, even you, who implants them all the time, you don't know if it's mechanical cut or laser cut?
A. I think that there's a way to know it. I just never looked at that box.
Q. But sitting here today, you can't think of what that way is?
A. Yeah, I look at the sling.
Q. Okay, you pull it out and you look at it, so you don't know until you open the box, pull back the, the plastic cover to figure out if it's laser cut or mechanical cut?
A. No, not with the plastic cover. You can actually see it on the sheet.
Q. But you have to open the plastic container to get to the TVTO, do you not?
A. No, it's transparent. You can actually see it without even opening it.
Q. Well, the body is transparent, the top is not transparent, is it?
A. The body, yeah, all the other sides are transparent.

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Q. The tub is transparent but the top is not?
A. No, the top is like a paper with a name.
Q. And you can look through the plastic tub and tell if it's laser cut or mechanical cut?
A. You can look at the sling in that area, yes.
Q. Without opening it?
A. Without opening it.
MS. GALLAGHER: Y'all are talking about different things. He's talking about the top of the box. Can you look through the top of the box and tell whether it's laser cut or machine cut?
THE WITNESS: No.
MR. FREESE: I understand what he was saying.
BY MR. FREESE:
Q. You're saying you can look through the clear plastic portion of the TVT before you even open the tub and tell if it's laser cut or mechanical cut?
A. I have used it so many times and I have, and there's a plastic cover in there, and you can see the whole device right through there. It's, it's, if I tell you, though, in order to be accurate with you, I

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cannot tell you that I look right through there and say, okay, which one is that, laser cut or mechanical cut.
Q. I'm asking you, are you able to do that?
A. I will have to look at it, because as I sit here today, I don't remember looking through it.
Q. When you open it and pull it out, it's got a plastic sheath on it, does it not?
A. It does.
Q. Well, can you see the edges?
A. Yes.
Q. And you can tell if it's laser cut or mechanical cut without ever pulling the plastic sheath back?
A. Yes.
Q. Okay. Is there any study that you have looked at that compared how laser-cut versus mechanical-cut mesh performs?
A. No.
Q. Do you order the slings, Doctor, that you implant in your patients?
A. No, the hospital orders it.
Q. When, when you order them, do you tell the hospital I need five TVTOs, or do you say, I need five TVTO laser cut or five TVTO mechanical cut?

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A. No, I have ordered just, just give me five TVTOs. Actually, you know, I don't tell someone I need TVTOs. Someone keeps my TVTOs there and, and, and I don't, I don't order like I would say that I order things for my office, no.
Q. Okay, but what I'm getting at is, when you, I mean, you are the doctor and if a TVTO is needed to be implanted in your patient, do you know whether or not it's a laser cut or mechanical cut?
A. Well, I look at it.
Q. At the time of the placement?
A. At the time that I have it there.
Q. Yes, sir, what I'm trying to find out is at the time that you buy it from Ethicon, are you dictating it be one or the other?
A. No.
Q. Who does that?
A. They, they, they order it from, from the company. There's no one that determines laser cut or mechanical cut.
Q. And it doesn't make any difference to you which one it is?
A. No.
Q. Am I correct that after the TVTO laser cut was introduced, Ethicon introduced several more

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synthetic sling products, correct?
A. I overheard on the, on the different conferences and activities by Ethicon that there was, they were talking about laser cut and mechanical cut. It never made a difference to me, laser cut or mechanical cut.
Q. And is that -- it's fair to say then that you've actually never studied the clinical differences between laser cut and mechanical cut?
A. No, there has been no actual clinical studies to my knowledge, and if you have something that I don't know, please, I will read it.
Q. Sure, and that's fine, Doctor, but my question to you is, and I think you may have told me, there are no studies comparing laser cut to mechanical cut and you have not endeavored in forming your opinions in this case to do any studies on the difference from a clinical standpoint of laser cut versus mechanical cut, correct?
A. To my knowledge, there has not been a randomized control trial comparing laser cut versus mechanical cut.
Q. Yes, sir, I understand that, and nor have you done any kind of literature search to see if there's any literature, even if it's not a randomized

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control trial, correct, about the difference between mechanical cut versus laser cut?
A. No, there's no -- I actually look for mechanical cut versus laser cut, and what I have is what's in the company documents.
Q. So the only documents you've looked at that discuss the difference between mechanical cut and laser cut is what the company lawyers supplied you?
A. Yes, the company documents.
Q. And you've done no other independent literature review or scientific review of any literature on any difference that may exist between laser cut and mechanical cut from a clinical standpoint?
A. I did an PubMed search and I could not find any.
Q. Okay. The only documents that you have looked at comparing laser cut to mechanical cut are the internal documents of Ethicon, correct?
A. That is correct.
MR. FREESE: Let's take a break.
(Break taken from 10:25 to 10:30 a.m.)
BY MR. FREESE:
Q. Dr. Sepulveda, before our break we were talking about laser cut versus mechanical cut, and real

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quickly, I am correct that after TVTO laser cut was introduced, Ethicon introduced TVT Secur, correct?
A. Yes.
Q. TVT Abbrevo, correct?
A. Yes.
Q. TVT Exact, correct?
A. Yes.
Q. Am I also correct that after TVTO laser cut was introduced, Ethicon never introduced another mechanically-cut synthetic midurethral sling again, am I correct?
A. I, I could not track, but I take it as you're telling me.
Q. You agree with me that TVT Secur is laser cut, correct?
A. Yes.
Q. Every version of it?
A. Yes.
Q. TVT Exact is laser cut, is it not, every version of it?
A. Yes.
Q. TVT Abbrevo is laser cut, every version of it, correct?
A. Yes.
Q. So you cannot think of a single

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midurethral sling that Ethicon manufactured after the introduction of TVTO that was anything other than laser-cut mesh, correct?
A. I cannot think of any other.
Q. And do you have any explanation why that was, why they don't make mechanically-cut mesh in any of the products once laser-cut TVTO became available?
MS. GALLAGHER: Object to form.
A. I did not know the reason for it.
BY MR. FREESE:
Q. Okay. Doctor, in your overview and review of literature, you say stress urinary incontinence is a common condition in women, and we can look at some data, but am I correct that, that AUA said that up to 50 percent of women will suffer some form of the SUI in their lifetime?
A. I read that, yes.
Q. And you agree with that?
A. I would agree with that.
Q. It's that common of a problem?
A. It is a very common problem, yes.
Q. You say all procedures, but in particular, you say earlier procedures, in other words pre, pre-midurethral sling procedures I gather is what you're talking about here?

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A. Yes.
Q. Carry the risk of urinary outlet obstruction, voiding dysfunction, major nerve and vascular injuries, pain, relatively high frequency of revision and wound healing complications?
A. Yes.
Q. No previous surgery prior to midurethral slings caused a risk of erosion, am I correct?
A. No, there was exposure of the sutures, we did see that, and we did see sutures inside the bladder.
Q. Okay. That's not my question. My question is that erosion of the midurethral sling is a, is a, is a complication unique to midurethral slings, synthetic midurethral slings, correct?
A. Yes, exposure of the tape was not seen before when tapes were not being used.
Q. Okay, and, Doctor, you say that Burch colposuspensions had earlier been associated with the term gold standard which established a clinical benchmark of efficacy for the treatment of SUI. You see that?
A. Yes.
Q. I'm read some of your prior depositions, so I'm going to try to speed through some of this.

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You're not a fan of the phrase gold standard, are you?
A. Never been much of a fan of that.
Q. So you're not going to come into court and start giving us opinions that the TVTO is the gold standard of anything, correct?
A. I would refer to anything that was referred before as a gold standard as the current clinical standard.
Q. Current standard, and in fact, there have been articles published in the New England Journal of Medicine that say you shouldn't use the word gold standard, you should use the word current standard, correct?
A. Yes, it was in -- I don't know if it was in the New England Journal of Medicine, but it was definitely in the AUGS Journal.
Q. Okay. And you agree that that's a more appropriate phrase to use?
A. Current clinical standard seems to be a more objective way of looking at things.
Q. And, so, when you come to San Antonio to testify, is it fair to say that you're not going to be sitting there pontificating about gold standards, that's just not a term that you think is appropriate?
A. I agree, I would not be pontificating

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about the gold standard.
Q. Okay, thank you. Doctor, you said that the studies in the medical literature prior to the midurethral sling, prior to the arrival of TVT were lacking and of poor quality. Do you see that?
A. Yes.
Q. And I'm just, I'm just trying to figure out, what is your basis for saying that the studies prior to TVT were of poor quality?
A. Well, there were, there were retrospective cohort studies that were case reports, there were groups of case reports, but there was a lack of randomized control trials.
Q. Is this just simply, and -- strike that.
The lack of a substantial number of randomized control studies is, is how you reached the conclusion that the study quality is poor?
A. Right.
Q. In other words, you have to have a significant number of randomized control studies in order to have good-quality data, in your mind?
A. I, I look at the, at the cohort studies and there are instances in which I may not have a randomized control trial. I would like to see multiple cohort studies if I don't have a randomized control

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trial.
Q. All right, and the reason I asked you about gold standard is because about three pages later you then invoke the gold standard language on the TVT.
A. I actually saw that on my report, and I, I apologize for that. That should be current clinical standards.
Q. Okay, and that's fine, and fair enough. So, even though you have it in your report, you won't be referring to the TVTO as the gold standard?
A. I'm going to repeat my answer, I will not be pontificating about gold standard. I will be saying current clinical standards.
Q. Thank you, sir. You have no idea how much time that saved us.
Doctor, when you say, quote, "The use of monofilament, non-absorbable polypropylene predominates in the current clinical practice," you're not distinguishing between mechanical cut and laser cut?
A. I'm not distinguishing between one or the other.
Q. Am I correct that in that sentence there, when you say that those monofilament non-absorbables predominate the current clinical practice, you're lumping mechanical cut and laser cut meshes together?

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A. Yes.
Q. Okay.
A. As they are available, because we don't have it available anymore in the mechanical cut.
Q. When did Ethicon stop making TVTO mechanical cut?
A. I, I, I cannot recall one specific date, no.
Q. So, let me clarify that. So, as of today, you think all TVTOs are laser cut?
MS. GALLAGHER: Object to form.
A. Yes.
BY MR. FREESE:
Q. And you don't know exactly when Ethicon stopped manufacturing TVTO mechanical-cut mesh?
MS. GALLAGHER: Object to form.
A. I don't know a specific date.
BY MR. FREESE:
Q. And is that why you said you don't concern yourself with it, because it's only laser cut, right?
A. It's only laser cut now.
Q. All right, thank you. Doctor, you say that, quote, "These anatomical considerations," and I'm on page 8 of your report if you want to follow along

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with me. Quote, "These anatomical considerations were well documented during the description and the design of the TVTO." Do you see that?

A. Okay, yes. These anatomical considerations were well documented during the description and design of the TVTO. I am talking about the hammock of the, in the suburethra and the periurethral tissue.

Q. All right, and we can agree that prior to the launch of the TVTO, there were no randomized controlled studies of that product done, correct?

A. No.

Q. Okay, and the product was launched in the U.S. and worldwide without a single randomized control study being performed by Ethicon, correct?

A. It was, it was released on a 510(k) approval.

Q. And, so, the answer to my question is, at the time the TVTO was released to the world by Ethicon, there were no randomized control studies demonstrating the safety or efficacy of the product, correct?

A. That's correct.

Q. And the prelaunch studies that Dr. de Laval performed didn't even use the same kit that became the TVTO, did it?

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A. I think that the needles were, were different.

Q. Okay. And he was, he was, he was cutting it himself, correct?

A. He may have cut it himself, I'm not aware of which methodology he used for that.

Q. Because there was no kit for him to implant in women, he created it, correct?

A. He created it.

Q. And just so we're clear, Doctor, my question may have lent us to RCTs. At the time that the TVTO was launched by Ethicon, there were no clinical studies whatsoever on the TVTO, correct?

A. There were, there were the studies from the, from the inventor, and there was data on the TVT.

Q. And I'm not talking about TVT now, because that's a different product, isn't it?

A. That, that is, there's a different site on the anatomy where it's inserted.

Q. And it's implanted differently, correct?

A. It is implanted different.

Q. You say there existed the de LaVal clinical data, correct?

A. Yes.

Q. But he's the inventor, correct?

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A. He's the inventor.

Q. And you know he had an economic stake in the results that he reported on his clinical data, correct?

A. Yeah, you know, I was asked the same question last week, and these are high-caliber investigators. I have no reason to believe that they are going to be biased specifically by money. I cannot say, I cannot sit here and testify under oath that I believe that that's the case.

Q. Okay. Well, I'm simply asking you, you recognize that the only clinical data that existed was that produced by the guy who had an economic stake in the outcome of these results, correct?

A. That's correct.

Q. Okay. And that data was based on his own pre-cut invention, not what ultimately became TVTO, correct?

A. His own device.

Q. In other words, de LaVal was using a homemade product when he was implanting women with the, the, his obturator-approach midurethral sling, correct.

MS. GALLAGHER: Object to form.

A. I don't think he made it at home. He may have made it elsewhere, but I --

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BY MR. FREESE:

Q. In his own lab is what I mean.

A. In his own lab, correct.

Q. Okay. It wasn't done in a factory like TVTO is made today, correct?

A. It wasn't manufactured by a third party, no.

Q. And have you reviewed the original launch plan that Ethicon prepared before the launch of the TVTO?

A. I went through a few papers because I believe it's included in that binder, and I reviewed them probably, I saw it about a year ago.

Q. Okay, and do you know the original launch plan Ethicon had was that they were going to do clinical studies before the TVTO was launched?

A. I can't recall specifically they were deciding to do clinical studies on TVTO.

Q. I'll make that representation to you. You don't have any reason to dispute that, do you?

A. No, no reason to one way or the other.

Q. And if the original launch plans anticipated Ethicon was going to conduct its own or independent clinical trials before the launch of TVTO, you would have no objection to that, would you?

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A. I would have no objection to, to, to that.
Q. So, because that would be the responsible thing to do, wouldn't it?
MS. GALLAGHER: Object to form.
A. No, they'll have their reasons to conduct their studies, and they have their, their own justifications to do whatever trial they may think. I believe that what, what determined that was what their interaction was between what was established between the FDA and Ethicon at that time.
BY MR. FREESE:
Q. And that's not really my question, Dr. Sepulveda. My question is, you would agree with me that the plan to do clinical trials before launching a product is a responsible thing to do, that plan itself, theoretically?
A. In general terms, you could say that doing clinical trials is a good idea, as long as those clinical trials don't put unnecessary subjects to demonstrate things that have already been demonstrated.
Q. Okay. And that's why you normally want to do clinical trials, right? You want to build a body of science that supports the safety and efficacy of your product, correct?

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A. Before I continue, I may have said unnecessary subjects. I mean as long as it doesn't put subjects through unnecessary risks. That's what I meant on my answer.
Q. Yes, sir.
A. And following with your question?
MR. FREESE: Would you read back my question? I'm sorry.
THE COURT REPORTER: And that's why you normally want to do clinical trials, right? You want to build a body of science that supports the safety and efficacy of your product, correct?
A. Yes, science built up on previous studies.
BY MR. FREESE:
Q. And you know that those clinical trials never occurred, correct?
A. I am not aware of those clinical trials happening.
Q. And you don't know the reason why they didn't occur, correct?
A. No, I don't know the reason.
Q. You said for whatever, whatever reason Ethicon had for not doing those clinical trials prior

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to the launch of the TVT is an Ethicon decision and you have no idea why they didn't do it?
A. That's going to be an Ethicon decision alone in their interaction with the FDA.
Q. Should the decision to not do clinical trials ever be based on simply wanting to rush your product to market? Should that ever be a basis not to do a clinical trial?
MS. GALLAGHER: Object to form.
A. No, I think that --
THE WITNESS: Did you get that objection?
MR. FREESE: She got it, don't worry. She's a big girl. You worry about you, she'll worry about her.
A. The decision, I believe whenever there are products like this that are innovative, that that decision is going to be again, what I already said, I'm not going to repeat, I mean, I will repeat what I already said, between Ethicon and the FDA, but it's also determined internally by Ethicon, by the different branches that are input in a project, because you may have marketing individuals, you may have sales individuals, you will have scientific individuals, you have engineers, medical liaisons, so you cannot, you cannot just point to one area. I believe that in every

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company, every device company, there's going to an interaction between all these different individuals deciding which, which product gets the studies done.
BY MR. FREESE:
Q. And I'm not quibbling with you about that, Doctor. My question was quite different. Do you agree with me, generally speaking, that, that a responsible medical device company shouldn't forgo clinical trials simply to rush their product onto the market? That's my only question.
MS. GALLAGHER: Object to form.
BY MR. FREESE:
Q. That would not be the responsible thing to do. You agree with that?
MS. GALLAGHER: Object to form.
A. It's going to be a decision of the company, but in general, in general, you don't, you don't rush things. You don't rush decisions for surgery, you don't rush decisions to place or take out implants. You don't rush in general any of these decisions.
BY MR. FREESE:
Q. And if the decision to forgo clinical trials was simply an economic decision and not based on safety or efficacy, we can agree that that would be

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something that Dr. Sepulveda would be critical of?
MS. GALLAGHER: Object to form.
A. If anything that is motivated purely by economics, it belongs in a different arena and not health care.
BY MR. FREESE:
Q. Thank you. Doctor, this is sort of a question we had started the last hour, but other than the life care plan, you said that you prepared the entirety of this report. Is that correct?
A. Yes.
Q. Did you prepare all the footnotes, too?
A. Yes, I did, I did, I did prepare those, those papers.
Q. And the reason I was curious is because the reports and the footnotes have a remarkable similarity to doctors from all over the country that work for Ethicon, Dr. Permugia and Dr. Grier and Dr. Flynn, I mean, we've got these reports and it's remarkable how similar your work is and their work.
A. I can tell you this, I spent a lot of time sitting down and writing. It has, there were a few other things that were added to it, there were things that have been edited by me on consultation with the attorneys, but there's, there's no attorney that is

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going to bring out a report that I don't, I don't approve.
Q. I'm not saying you don't approve, but, I mean, you sat down and actually put all these footnotes in your report?
A. Yeah, actually the footnotes, I remember exactly going through the two papers on the frequency of these devices, I remember going through all the papers that I have saved over time, and there are other papers that were given to me about randomized control trials. I wrote this, I wrote this just after, just after my, my board, my subspecialty board certification.
Q. Did you cut and paste any of this report from another report?
A. No, I wrote a report, I submitted it, and then they came back with extra, extra bibliography, but I actually submitted a bibliography.
Q. Okay, you said they came back with a bibliography. You're talking about the footnotes, correct?
A. No, if there's a footnote, if there's a citation, there's a citation, I look at these citations, and the ones that were submitted, I look at them before they came.

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Q. My question is, was any of this report cut and pasted from any other report, or was this all original work product as of March 23rd, 2016?
A. No, my report on TVTO is my report on TVTO, and if it looks like Christina Permugia's report or whoever report, it's what's available there. There are no more papers.
Q. But what I'm saying is this, I won't find any, any language in your report that, in any report prior to March 23rd, 2016, correct, because this is all your work product, so I won't be able to go and find any reports prepared by you that looks identical, in fact is identical in the entire report, because you created this on March 23rd, 2016, correct?
MS. GALLAGHER: Object to form.
A. I did not create this on March 23rd. This has been written and reviewed over the last year and a half, two years.
BY MR. FREESE:
Q. When did you start writing your Ramirez report?
A. Over a year ago.
Q. How many hours do you have in the Ramirez matter?
A. Lot of hours. I mean, this is probably

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the case that has taken the longest number of hours.
Q. And so what is that?
A. I put it together and I submitted as a whole group. Let me tell you, when I started seeing this, this, these cases, I had like four or five cases that I was reviewing, and, then, I was asked to do a report on Ramirez. There were other cases that did not require a report. That's how I know that I, I recall sitting weekends and going, and writing this.
Q. I just haven't seen a Ramirez invoice. Have you prepared one?
A. I believe that there are a few with Ramirez numbers.
Q. But do you have a total Ramirez invoice somewhere?
A. They were submitted last -- well, that's, that's, there was a time in which I say no, we want you to put for each specific case, and that's when I started doing it, a few months ago, that was for Ramirez, and I was here with, with Mr. Schnel last week and he had, he had those documents.
Q. Do you have your Ramirez invoice with you?
A. No.
MS. GALLAGHER: You already have them.

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They were here we when started the depo.
MR. FREESE: Where are they?
THE WITNESS: These are my invoices.
MR. JORDAN: There were two exhibits to the letter that Chris Morris sent. One of them you were asking to be blown up. The other is the invoice.
MR. FREESE: Right.
BY MR. FREESE:
Q. These don't break down Ramirez. Are these all Ramirez invoices?
A. No, there's a group, it's grouping all the MDL cases, the most recent ones.
Q. But you can't tell from these invoices what they're for?
A. Yeah, I just group all the hours on there.
Q. How many hours do you have in your best judgment on the Ramirez matter?
A. I would say over, over a hundred hours.
Q. Over a hundred hours on Ramirez?
A. Yeah, easily.
Q. And that doesn't include your MDL time?
A. Nor my MDL.
Q. I'm going to mark as the, the cover

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letters from, the payments from Ethicon and the invoices here as Exhibit 7 to your deposition. Okay?
A. Okay.
(Plaintiff's Exhibit No. 7 was marked for identification.)
BY MR. FREESE:
Q. When doing your report, Dr. Sepulveda, did you attempt to look and see how many of the authors that you were citing in support of your opinions were paid consultants by Ethicon?
A. No.
Q. Do you even know how many of these authors you cited are paid consultants of Ethicon?
A. No.
Q. And were paid consultants at the time they wrote their reports?
A. I do not know that.
Q. Is that a fact of no consideration of yours, you don't care?
A. No, the methodology takes care of whatever bias to be introduced.
Q. Well, assuming one knew what the methodology was.
A. Yes, there's a methodology, there's auditing on research projects, there's supervision,

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procedures manuals, there are lab manuals. So this is not, there are people looking over each other's shoulders on research projects. So that's what I call, what I call about the methodology is not only the methodology for the randomized control trial but also the surveillance on it.
Q. Who was overlooking Dr. Ulmsten's study, for example, on TVT? Who is looking over his shoulder?
A. I don't know who was looking at him.
Q. Nobody was. You know that, don't you?
A. No, I don't.
Q. You realize that nobody was overlooking Ulmsten's studies?
A. No, I don't know that.
Q. Well, can you name me one person who oversaw what Dr. Ulmsten prepared?
A. No, I just don't know who overlooked.
Q. Did you ever look at the patient level data for Dr. Ulmsten?
A. No.
Q. Did you know that Ethicon never even looked at the patient data for TVT studies that Ulmsten did?
A. No, I do not know how Ulmsten conducted his research, his research project.

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Q. Am I correct that you have not looked at the patient level data of any of these authors that you're citing in your report?
A. No, that's not correct. I have looked at, at these reports and I look at the methodology that they have used.
Q. I'm not asking that. I'm talking about, I know you've looked at the methodology. Have you looked at the patient level data that the authors were looking at when they write these reports?
A. Define patient level data.
Q. The actual data that's collected at the sites for these trials that are being performed.
A. How it was collected?
Q. Yes, sir. Have you ever gotten the patient level data of any of these studies?
A. No, it's not described on the report on any papers, any research papers.
Q. You simply take what the authors say and give credit to what they say, assuming that they have given credible, reliable, unbiased results, correct?
A. They -- I don't assume. I read the papers, and I read papers that have more accuracy than others in methodology, but that's why there's a section on methodology on each paper.

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Q. And you see what the methodology is and then read it, decide you like it, and then cite it?
A. I decide if I find it accurate, yes.
Q. You say on page 4 of your report: Overall, there are over 100 randomized control trials that have accumulated and countless more cohort studies on TVT and TVTO. Do you see that?
A. Yes.
Q. We can agree, you've lumped TVT and TVTO there in that sense together, have you not?
A. Yes.
Q. And we've agreed that they're two different products, correct?
A. The insertion is different.
Q. And they're different products?
A. They are different products because the insertion is different, the needles are different.
Q. And they have different clearance applications, correct?
A. They have different clearance applications.
Q. The TVT was cleared using ProteGen as the predicate product, correct?
A. Yes.
Q. So when you say a hundred randomized

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control trials, we can agree that you didn't mean to suggest to the reader of this that there are over 100 randomized control trials of TVTOs. We can agree on that, can we not?
A. No, of TVT and TVTO.
Q. Yeah. So, my question to you is, you agree with me that there are not over 100 randomized control trials of TVTO, correct?
A. That is correct.
Q. And if you then looked and said I want to know how many -- first of all, do you know how many randomized control trials of TVTO exists?
A. It's in the Cochrane paper, and I do have an abbreviated portion of the Cochrane and I can refer to it.
Q. All right, without referring, do you have a judgment how many randomized control trials of TVTO exists?
A. No, it's in the Cochrane. If I would have asked, if a patient would come and ask me that question I would say I will have to look at the Cochrane review.
Q. Do you have the Cochrane review with you right now?
A. Yes.

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Q. Why don't you grab that.
MR. FREESE: Let's go ahead and mark that, let's slap Exhibit 8 on there.
BY MR. FREESE:
Q. And would you tell us what you're looking at there, sir?
A. I'm looking at the review article from Neurourology and Urodynamics from 2011, and I should have an updated version in my reliance list.
Q. Okay. Do you know whether or not this was the one that the FDA was looking at in the white paper?
A. Most likely that's the one that they were, they were looking at.
Q. Because it's 2011?
A. Exactly. I don't have the 2016 easily marked in here. I know it's in this pile.
Q. Let's try to work on this. If you think it's substantially different, then we can maybe find it during a break. Does Exhibit 8 answer your question that I -- does it answer my question? Do you want me to remind you what my question is?
A. It's how many randomized control trials are on TVTOs?
Q. Yes, sir.

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A. Okay, they found 24 trials.
Q. Where are you looking?
A. Right here.
Q. Okay. Are you saying 24 trials address the comparison of transobturator route versus retropubic route?
A. Yes.
Q. And then it has those cited. Okay, now, let me ask you further, of these 24, of these 24 randomized control studies, they weren't all TVTO studies, were they? They were comparing retropubic versus obturator approach, correct?
A. Right.
Q. So, of those 24, not even all 24 of those are dealing with Ethicon's TVTO, is that correct?
A. No, there's, to do a randomized control trial, if it would be just TVTO, it would be a cohort study. If it's a randomized control trial, you have to have two arms, and with those two arms classically what we have is the retropubic and the, and the TVTO. The biggest study on that is the TOMUS, T-O-M-U-S, the TOMUS trial.
Q. But my question is, some of these 24 studies are not even studying the Ethicon TVTO, they are simply comparing midurethral slings that are using

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an obturator approach, it may not even be Ethicon's products being studied, correct?
A. There are two, they made two comparisons in the Cochrane data review. They made a comparison between transobturator slings and they made a comparison between retropubic and transobturator slings.
Q. And not necessarily even Ethicon's transobturator slings, correct?
A. Yeah, they compared different ones.
Q. And, so, am I correct, you cannot sit here today, Dr. Sepulveda, and tell me how many randomized control studies have been done looking at Ethicon's TVTO? Can you agree that you can't tell me that number?
A. I can, I can say for certain, without looking into the long version, this is the short version of the Cochrane data review, I can say with accuracy the TOMUS trial.
Q. One?
A. Yes.
Q. Okay. I'll mark Exhibit 9 to your deposition, which is the, do you recognize that as the white paper?
A. Yes, the FDA Executive Summary.

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(Plaintiff's Exhibit No. 9 was marked for identification.)
BY MR. FREESE:
Q. And you've looked and relied upon this, did you not, in forming your opinions?
A. I read it and it just allow me to understand. There was no specific cite on my opinion that refers to, to that paper.
Q. But you actually showed up to your deposition with a highlighted copy of it, did you not?
A. No, I -- yes, I actually did have a highlight copy, but the only data, the only place in which I refer to the Executive Summary from my report is when I, when I speak about the MAUDE database.
Q. Let's talk about something different, though. Let me show you Exhibit 9, page 42, of the FDA Executive Paper.
Now, you've -- and before we get to that, your testimony is you relied on the Cochrane report in forming your opinions today about the safety and efficacy of TVTO, am I correct?
A. And the Cochrane report and the TOMUS trial and the Tommaselli analysis.
Q. And the FDA had some comments about the Cochrane review, did it not?

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A. Yes, they did have an opinion here.
Q. And it says in the first paragraph, under conclusion, safety of mesh used in repair of stress urinary incontinence based on published literature. Do you see that?
A. Yes.
Q. Quote, "The Cochrane reviews are limited in the ability to fully evaluate the safety of profile of the surgical mesh used in SUI patients. The main objective of these reviews is to evaluate the effectiveness of the SUI procedures using randomized control trials that have compared a mesh procedure to another approach." Do you see that?
A. Yes.
Q. So, the FDA was criticizing the reliability of the Cochrane reviews from a safety standpoint, correct?
MS. GALLAGHER: Object to form.
A. That is, that is, that is correct. They disagree with the methodology.
BY MR. FREESE:
Q. I accurately read what the FDA said about the Cochrane reviews that you are relying on, correct?
A. Yes, they, I think that, when you look --
Q. Hold on. I don't mean to cut you off,

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but I'm simply asking you, did I accurately read to you just now what the FDA's conclusion was of the Cochrane reviews?
A. That's what they described, yes.
Q. If you'll drop down three paragraphs, it says, quote, "The Cochrane reviews did however identify noteworthy differences between mesh procedures and open colposuspension. The risk of perioperative complications favored colposuspension compared to all sling procedures combined, and the risk of voiding dysfunction was similar between colposuspension and the TVT sling." Do you see that?
A. Yes.
Q. Did I read that correctly?
A. You read that. I didn't follow word by word, but you...
Q. Okay, and that's, that's contrary to the opinion that you've expressed in your report, is it not?
A. That's, the Cochrane review and the most recent Cochrane review and the TOMUS report are what's used in my report, and there's, I was looking for my 2015 Cochrane review, and I just found it.
Q. Okay, and we'll get to that, but let me finish my question here. You agree with me that the

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FDA concluded that the, the Cochrane reviews that you have relied on were noteworthy because they found, in the view of the FDA, that the risks of perioperative complications made mesh less safe compared to colposuspension, correct?

A. But that's not what it says on the Cochrane review.

Q. That's what the FDA concluded after reading the Cochrane review, correct?

A. Yes, but I don't know how they came to that conclusion.

Q. And you understand, Doctor, what the FDA was doing in 2011 when they prepared this white paper, they were doing a systematic review of all known literature, were they not?

MS. GALLAGHER: Object to form.

A. Yes, but that's not what's been published on the summary.

BY MR. FREESE:

Q. But what I'm saying, you understand that's what the FDA undertook to do? They undertook to independently collect all known literature on the safety and efficacy of midurethral slings and draw some conclusions from those studies, correct?

A. If they did a systematic review, I have

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not seen any publication about the systematic review made by the FDA, because the document that you have in front of you is an executive summary, it's not a systematic review report.

Q. Would you look at the second paragraph, sir?

A. Yes.

Q. Okay. Quote, "The FDA's systematic literature review found that the weighted average rates of urinary problems, re-surgery rates and perioperative organ perforations were similar to overall rates presented in published meta-analyses and systematic reviews." Do you see that?

A. Yes.

Q. They're saying they did a systematic literature review.

A. Yes, they say that.

Q. Do you dispute that they did a systematic literature review?

A. I don't dispute they did it. I just have not seen the document.

Q. Well, we're looking at the document.

A. No, this is not a report of a systematic review.

Q. This is the report of the review.

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A. This is not a report of a systematic review. This is an executive summary.

Q. Have you looked at the systematic review?

A. I have not seen a systematic review.

Q. So you're not saying that the systematic review came to any different conclusion than what the summary did, correct?

A. Well, I have not seen it.

Q. Okay. But you disagree with the conclusions they reached regarding the Cochrane reviews?

A. Yes, I do disagree.

Q. Okay. So, in your view, at least in this respect, Dr. Sepulveda, you would say that the FDA got it wrong in their conclusion regarding what the Cochrane reviews showed about complications from midurethral slings, correct?

A. Yes, and I base my, my answer on the last, on the last statement on the review article, that says that monofilament tape has significantly higher objective cure rates, and the obturator use wasn't less favorable than retropubic, but only on an 84 to 88 percent --

Q. That's on the cure rates, though.

A. That's on cure rate.

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Q. We're talking about complications right now.

A. Yes, we go through that. However, there were less voiding dysfunction, blood loss, bladder perforation with the obturator route.

Q. Compared to what?

A. Compared to colposuspension, pubovaginal slings and retropubic procedures.

Q. Doctor, let's move up a paragraph here. In the Cochrane review, minimally-invasive synthetic suburethral sling operation appeared to be as effective as open retropubic colposuspension, correct?

A. Yes.

Q. That's talking about efficacy, correct?

A. Yes.

Q. But that it had significantly more bladder perforations, correct?

A. There were more bladder perforations when we compare, when you compare colposuspensions with retropubic slings.

Q. Doctor, I'm going to mark as Exhibit 10 to your deposition the actual appendix to the published review of literature that we've looked at with the FDA.

(Plaintiff's Exhibit No. 10 was marked for identification.)

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BY MR. FREESE:
Q. Do you see, you've seen this was actually part of the Executive Summary. Correct?
A. Yes.
Q. And it says the FDA evaluated the peer-reviewed scientific literature to revisit the fundamental question of safety and effectiveness for surgical mesh for POP and SUI, correct?
A. Yes.
Q. A systematic literature review was conducted by searching the PubMed database from January, 1996, to April, 2011. Do you see that?
A. Yes.
Q. I won't read you all this, but this says what the FDA actually did, correct?
A. Yes.
Q. You have no reason to dispute that they actually did what they say here in Exhibit 10?
A. I have no reason to dispute that's what they do.
Q. You just dispute some conclusions they reached?
A. Yes, I think that the Cochrane review, with all the possible limitations that any study would have, have less limitations than the FDA executive

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report.
Q. Even the FDA said the Cochrane review results were only of moderate value, did they not?
A. Well, there's no standardization of statistical analysis done in concluding that, if they say that.
Q. Well, they do that say that, don't they? They said that the strength of the Cochrane data is moderate. That's how way they described it, did they not?
A. Yes, most of it is not moderate.
Q. And, Doctor, back to page 43 of the executive study.
A. Yes, I have that right here.
Q. The FDA said that in the systematic review of the literature conducted by the FDA and based on adverse event reports in the MAUDE database, there's a potential for serious complications with mesh products indicated for SUI repair. Do you see that?
A. Yes.
Q. Do you disagree with that?
A. No, they actually table it, they actually got the frequency, and they actually mentioned the limitations of the MAUDE database. So, that's, I find this, this statement to be overreaching. I think that

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this, the fact that we're looking at an executive summary and the fact that we don't have a systematic review publication just speaks for itself in looking at the overreaching of these conclusions.
Q. And this goes on to say, quote, "The FDA is concerned that the safety outcomes may not have been comprehensively evaluated by the randomized control trial to date and that the safety of SUI repair with mesh needs to be further considered in evaluating the overall risk-to-benefit profile of these products." Do you see that?
A. And it was actually further considered.
Q. Did I read that correctly?
A. Yes.
Q. Okay, and do you agree with that conclusion?
A. Yes, it needs to be further considered. I do agree with that. And it was further considered.
Q. And you agree that the comprehensive review of the RCTs may not have been able to comprehensively capture all of the safety data on the midurethral slings?
A. No, the RCTs will have established benchmark for safety.
Q. Well, the conclusion was that they didn't

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comprehensively gather the safety data, the RCTs didn't.
A. That's the executive summary conclusion, but that's not the conclusion of the mesh analysis done by the Cochrane review.
Q. Again, that's the conclusion of the FDA that you disagree with?
A. That's what they state and I disagree with it, yes.
Q. And let me just ask one more question and we'll move on to something else. So, now that we've gone through this discussion here, Dr. Sepulveda, we can agree that the only long-term randomized controlled study of TVTO that you're aware of is the TOMUS study?
A. No, I am aware of the, of the study done by Cloe in 2013, which is a randomized control trial of the TVT and TOT. I'm also aware of the RCT comparing TVT and TVTO of Aniulene, which is a prospective randomized control trial of TVTO and TVT.
Q. Over what period of time?
A. On 264 women.
Q. For how long?
A. For -- I cannot answer that question based on this, on what I have.
Q. So you can't tell if it's a long-term

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study or not?
A. Well, it's a randomized control trial that looks at safety of the TVTO. I also have, and these are from the new Cochrane review which I found, the one from 2015. I have TVTO being compared to TOT in 2008.
Q. How long?
A. That's a three month, three month.
Q. That's not a long-term study, is it?
A. No, there are other longer-term studies.
Q. But we can agree that three months is not by anybody's definition a long-term study, correct?
A. No, that's a study just about safety.
Q. First of all, you're looking at the 2015 Cochrane review?
A. Yes.
Q. Okay. As you sit here today, Doctor, can you tell me how many long-term randomized control trials there are of TVTO --
MS. GALLAGHER: Object to form.
BY MR. FREESE:
Q. -- whose primary end point is safety?
MS. GALLAGHER: Object to form.
BY MR. FREESE:
Q. How many of those exist?

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A. I'm just looking through them.
Q. Listen to my question. How many of those are long-term studies, what I mean by that, five years or more, how many long-term, controlled, randomized controlled studies of TVTO exist, five years or greater, with the primary end point of safety? How many of those studies?
A. Well, I've already gone through three of them, because there's also the Chen study.
Q. How long is that?
A. This was 12 to 24 months.
Q. That's not five years. Doctor, listen to my question. Close the book, you've got to look at me and listen to my question because I think you're getting distracted. Do you know how many randomized controlled studies, long term, by which I mean longer than five years, and whose primary end point was safety, are there dealing with TVTO?
A. No, I do not, I do not recall the specific number of them and I know there are trials at five years, seven years, and ten years.
Q. Okay.
A. There are trials in here, and I have it in my reliance list, but if you're asking me just to recall as a memory test, no, I do not recall that.

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Q. Okay, and in those five-, seven- and ten-year trials, the primary objective was safety. Is that correct?
A. Safety.
Q. As opposed to efficacy?
A. Safety and efficacy is evaluated on both, but now that you mention, the TOMUS trial was safety and efficacy. The Tommaselli medium-term and long-term following midurethral slings, which is a systematic review of meta-analysis as the highest level of evidence, was at 36 months and at 60 months.
Q. Okay. So, there's one at 60 months, correct?
A. I can, I can continue looking, looking for it, on the different ones, but --
Q. That's fine, and this is not a memory test, and I'm sure your lawyer will be happy to walk you through when we get to the courthouse, but just sitting here right now, you can't name me one study that meets the parameters I just defined, correct?
A. Yes, I just, I just mentioned them to you.
Q. Which, TOMUS?
A. Tommaselli.
Q. Tommaselli?

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A. TOMUS trial, which is the best designed and most accurate trial that have ever been done with TVT and TVTO. There's the, there's Chen.
Q. Chen was five years or greater?
A. That's less.
Q. Doctor, we're not getting -- it has to be five years or greater. That's all I'm asking you. How many studies, TVTO, five years or longer, that study the safety of the device?
MS. GALLAGHER: Object to form.
A. I, I already say that I cannot recall one specific number.
BY MR. FREESE:
Q. And we can agree that it's way less than a hundred, correct?
A. It is less than, than a hundred.
Q. It's way less than 24, is it not?
A. It might be more than 24 now.
Q. As you sit here right now, you're unable to name one.
MS. GALLAGHER: Object to form.
BY MR. FREESE:
Q. Correct?
A. I said I cannot recall it.
Q. That's fine. That's all I want to know.

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Sitting here right now, you cannot name one.
MS. GALLAGHER: Object to form. He's already told you about three.
MR. FREESE: Counsel.
A. I already told you the studies that I can recall, and I looked at them and I gave you my best effort to give you that information.
BY MR. FREESE:
Q. All right. And of the TVTO studies that you rely on, Doctor, can we agree that none of them make a distinction between laser cut versus mechanical cut?
A. Yes, that has been established already.
Q. Even the doctors who did the study don't say whether or not the patients they are studying were implanted with laser-cut versus mechanical-cut TVTO, correct?
A. That's correct, there's no definition of it.
Q. And you don't know?
A. No, I don't know because they did not disclose it.
Q. And if there's in fact a clinically significant difference in safety between mechanically-cut TVTO and laser-cut TVTO, it won't be

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discernable from the studies, will it?
A. No, it's not discernable from the studies. That has not been defined.
Q. That has what?
A. That has not been defined.
Q. Okay. Doctor, would you look at page 14 of your report?
A. Yes.
Q. I just want to ask you real quick, the bottom of the first paragraph there, it says no medical certification of these complications or diagnostic confirmation was required on this report. Do you see that?
A. Yes.
Q. Would you just -- I don't understand the sentence. Can you tell me what that means?
A. Before we, we saw TVT and before we saw TVTO, before we actually saw midurethral slings, the quality of the studies were not, were not strong. We, we actually saw the first comparison between pubourethral slings and colposuspension in the, in the Alba trial published in the New England Journal of Medicine, but until then there was a very weak, very, very small cohort studies establishing the safety and efficacy of Burch colposuspensions and pubovaginal

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slings.
Q. It goes on to say, quote, "Surgical experience made clear that patients treated with TVT had less voiding dysfunction, less wound complications and less retention than the historic numbers from patients treated with pubovaginal slings, needle procedures or retropubic procedures." Do you see that?
A. Yes.
Q. You don't cite anything for that statement, do you?
A. No, but I --
Q. Hold on, I'll ask, you don't cite anything for that statement?
A. No, sir, I don't.
Q. And you're referring to TVT studies, not TVTO studies, correct?
A. I'm referring to TVT studies and I'm referring to TVTO studies.
Q. Well, it says TVT. The sentence says that surgical experience made clear that patients treated with TVT. That's a different product than TVTO, is it not?
A. Okay, we keep saying that it's a different product. I have the impression that we're going to be looking at those different products through

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the course of the day. So, do you want me to go through the, and I'm sure if you want you'll probably ask, but in which regard are we defining those differently?
Q. Well, if I said give me a TVT and give me a TVTO, we would have to have two different boxes, wouldn't we?
A. Yes.
Q. Okay, because they're two different products, correct?
A. They're two different products in the insertion needles, yes.
Q. They were cleared in a different way?
A. They were cleared in a different way.
Q. They had different predicate products?
A. Yes.
Q. That's what I mean by they're different products. So, when you're citing a TVT study, that's not a study of TVTO, correct?
A. That's, that's not necessarily a study of TVTO. That's a study about the tape.
Q. That's my point. When you cite a TVT study, it's not a study of TVTO, is it?
A. No, if I cite a TVT study, I'm citing that. TVTO is TVTO. But, yes, the surgical experience

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showed that there were less complications with pubovaginal slings or colposuspensions.
Q. Against TVT?
A. Against TVT, and when TVTO was compared to TVT, there was less.
Q. But your sentence doesn't even mention TVTO, is my only point.
A. I did not mention TVTO in that sentence.
Q. I mean, is the point you're trying to make, Dr. Sepulveda, that, that you, you like to use TVT and TVTO studies interchangeably because they involve the same polypropylene mesh?
A. Well, there are more similarities than differences.
Q. But is it because they use the same mesh?
A. No, not necessarily just the same mesh.
Q. Well, is that one of the reasons why you use the studies interchangeably?
A. Yes, you can actually use one or the other, but I don't even need to refer to TVT. TVTO has been shown in randomized control trials has been as effective and safer than TVT.
Q. Okay. And, so I guess it would be a fair comparison to compare TVT Secur to TVTO, right, because it uses the same mesh?

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MS. GALLAGHER: Object to form.
A. We're not talking about TVT Secur now. We can talk about how TVT Secur, and I have provided testimony before about how TVT Secur shares similarities with previous generations of TVTs.
BY MR. FREESE:
Q. They share the same mesh, do they not?
A. They do.
Q. As does Abbrevo, that has the same mesh?
A. That has the same mesh, right.
Q. So, basically, Doctor, on page 14, all these numbers and results of studies you're referring to, these are all TVT studies, are they not?
A. These are TVT studies.
Q. They're not TVTO studies.
A. And whatever complication might be reported from TVT is not going to be higher on TVTO.
Q. That's not my question, sir. Everything you're quoting here in your report are TVT studies, not TVTO studies?
A. These are TVT studies, right.
MR. FREESE: Let's take about two minutes. I want to grab some exhibits real quick.
(Break from 11:35 a.m. to 11:45 a.m.)

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BY MR. FREESE:
Q. Now, Doctor, am I correct that Prolene mesh is the mesh that's used in all TVT products, correct?
A. Yes.
Q. And that's the original old construction Prolene, correct?
A. That is the construction of Prolene and, and it's to the same degree of crystallinity that the, of Prolene sutures.
Q. I'm not asking about sutures right now, we can talk about that in a minute, but am I correct that the Prolene that is in the TVTO is the same Prolene that was used in Dr. Ulmsten's original TVT product?
A. It's the same construction Prolene. I cannot recall if the exact crystallinity or purity or analysis from Ulmsten. I don't think that he did that.
Q. Well, you know that the formulation for Prolene mesh has not changed since the original TVT produced by Ethicon, correct? And what I'm asking there is, the same mesh that's in TVT is in TVTO, is in TVT Abbrevo, TVT Secur, TVT Exact. Correct?
A. Yes.
Q. Okay. And that is a, that is a

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small-pore, heavyweight mesh, is it not?
A. No, it's not small pore.
Q. You think it's a large-pore mesh?
A. It is a large pore.
Q. And do you think it's a heavyweight mesh?
A. It's, in all, of all the applications that I use for midurethra, it's a lightweight mesh. When it's compared to the meshes for prolapse, it's on the heavyweight, it's close to the heavyweight, but not at the level that was the old meshes for hernias.
Q. Well, the old hernia mesh is Prolene, correct?
A. The old hernia mesh is Prolene.
Q. Okay. So, you're agreeing that the Prolene mesh is heavyweight mesh?
A. The Prolene mesh is heavyweight, yes. The Prolene that was initially described that we had 20 years ago, that's heavyweight.
Q. Well, what is used today is heavyweight mesh, is it not?
A. No, the fiber is lightweight.
Q. You think the fiber in the TVTO is lightweight?
A. Yes.
Q. And you think it's large pore?

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A. It's large pore.
Q. What is the basis for that opinion?
A. The large pore is over 75 microns, and the pore size on the mesh for TVT is 1,200 microns.
Q. That's an AMI classification that you're using?
A. That's on the AMI classification, which we know has its own limitations, but that's the only one that we have to compare the, the large pores with the small pores.
Q. The sole basis of you describing Prolene as large pore and lightweight is the AMI classification?
A. Yes, on the, on the slings, on the monofilament polypropylene slings, this is one of the largest pores.
Q. I'm just asking the sole basis for your opinion on that is the AMI classification?
A. No, that's not the sole basis. It's also the fact that it's a large pore, it's over 75 microns, and even when you define larger pores at 200, 300, it's still a lot larger than that.
Q. I'm asking you what is your basis for 75 microns, other than the AMI classification?
A. For the classification of 75 microns, it

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is the AMI classification.
Q. So, if I say, Doctor, what is the basis of your opinion that Prolene mesh is lightweight and large pore, you would say AMI classification, correct?
A. That's, that's the only classification that defines pores.
Q. And you have no other basis for that opinion other than that?
A. I would not have any, any other on that specific pore size.
Q. You understand, Dr. Sepulveda, that the engineers at Ethicon disagree with you, do you not?
A. No, I --
MS. GALLAGHER: Object to form.
A. I cannot base, that's an ambiguous question. I don't know which way they would disagree or what they're saying.
BY MR. FREESE:
Q. I'm asking you, have you ever seen any internal Ethicon documents describing the Prolene mesh as heavyweight and small pore?
A. They -- no, I don't, I don't, I haven't seen anything as small pore.
Q. Okay. So, if I looked through your TVTO company documents selected for your review by the

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company, I wouldn't find any internal documents in there saying that Prolene is small pore, heavyweight, would I?
A. That would be the basis of the disagreement of the engineers with me. So if there's a document in there, I would like to see it.
Q. I'm asking you, Doctor, if I look through here, as you sit here right now, you don't remember them supplying you with any internal documents where the scientists and the researchers at Ethicon repeatedly described their Prolene mesh as heavyweight and small pore? It's not in that binder, is it?
A. I don't recall it being in the binder, no.
Q. And as you sit here, you don't have any recollection that they supplied you any such documents stating that Prolene is heavyweight and small pore?
A. No, I do not.
(Plaintiff's Exhibit No. 11 was marked for identification.)
BY MR. FREESE:
Q. Now, I'm going to show you what I've marked as Exhibit 11 to your deposition. And do you see this chart here, Doctor?
A. Yes, I do see it.

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Q. Have you ever seen this chart before?
A. No.
Q. Okay. You see where it has type of mesh, microporous, medium, and macroporous?
A. Yes.
Q. Can we agree microporous means small pore and macroporous means large pore?
A. We can agree on that, yes.
Q. All right, and, then, you see where it says hernia?
A. Yes.
Q. And then you see where it EWH&U? Do you see that?
A. Yes.
Q. Is that abbreviation for Ethicon Women's Health?
A. Yes.
Q. And if you look at the first page, you'll see that this document came out of Ethicon's internal files, correct?
A. Yes.
Q. Because it bears a Bates stamp number from the company, correct?
A. That's correct.
Q. And under microporous meshes, does the

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document list Prolene as a microporous mesh?
A. This documents list Prolene as microporous.
Q. And it's not just talking about hernia mesh, is it?
A. No, it does mention TVT slings.
Q. Okay. That includes TVTO, doesn't it?
A. It just says TVT slings, in plural.
Q. Which would include the entire family of TVT slings, correct?
MS. GALLAGHER: Object to form.
A. I cannot testify to that because there's no date on this document and there's no specification of TVTO or TVT or any other TVTs.
BY MR. FREESE:
Q. Well, because TVTs all use the same mesh, do they not?
A. TVTs use the same, and all the products use the same mesh.
Q. So, when it says TVT slings, that includes the entire family of TVTs, right, because they all use the same, and have always used the same mesh?
A. Yes, but all it says is TVT slings.
Q. Right, and they're talking about the mesh being microporous. You see that?

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A. Yes.
Q. And you've never seen this document before, have you?
A. No.
Q. The lawyers didn't show it to you, did they?
A. I, I just, I just haven't seen it.
Q. You disagree with that description, I gather?
A. I do.
Q. Okay. And it says macroporous, and it has Vypro, Vypro II, Ultrapro. Do you know what those are?
A. Yes.
Q. Those are, Ultrapro is the mesh that was used in Gynemesh Plus M and Prolift Plus M, correct?
A. Yes.
Q. And you're familiar with those products, correct?
A. I am familiar with them.
Q. You implanted Prolift repeatedly, did you not?
A. I did.
Q. And that used a lighter-weight, large-pore mesh, did it not?

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A. It used a light, lighter weight, yes.
Q. And the lighter-weight, large-pore Ultrapro mesh has been available to the market since at least 2003, has it not?
A. I don't know exactly when. You're talking about the Ultrapro?
Q. Yes, sir.
A. No, I don't know when that was available on the market.
Q. You know it was years before 2010, though?
A. No, I do not know that.
Q. You don't know, you have no clue when Ultrapro was put on the market?
A. No.
Q. Okay. Do you, you, you've implanted Prolift Plus Ms, have you not?
A. Yes.
Q. Okay. That's a partially-absorbable mesh?
A. That's a partially-absorbable mesh, yes.
Q. And you know you were implanting that years before 2010, correct?
A. I did not use Ultrapro.
Q. Okay. When did you use Ultrapro?

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A. I used the polyglecaprone polypropylene mesh when it became available with Gynemesh. I'm sorry, with Prolift Plus M.
Q. What mesh was Prolift Plus M?
A. Polyglecaprone polypropylene.
Q. Okay. That's partially absorbable, is it not?
A. That's partially absorbable.
Q. It's a lighter-weight mesh, is it not, than Prolene?
A. It's heavier when it's implanted. It just gets lighter as the polyglecaprone component is absorbed.
Q. Because it absorbs and becomes a lighter mesh, correct?
A. Yes, it's lighter when you, when you take it out, and you measure after the polyglecaprone component, it's lighter.
Q. And the pores on the Ultrapro are considerably larger than they are in the Prolene, are they not?
A. I don't know exactly in the product of Ultrapro, and I don't want to infer from one product to another on these, on these devices.
Q. You've implanted all of them, Prolifts,

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TVT slings, correct?
A. Yes.
Q. And you know that they have considerably larger pores in the Ultrapro than the TVT Prolift.
A. You're asking about Ultrapro, but if you ask me about Prolift Plus M, we'll have a better understanding of it. I just don't want to give testimony on Ultrapro that is used for hernia.
Q. Okay. I see the distinction. Let me clear it up. You know that Ultrapro mesh is used in Prolift Plus M?
A. It is polyglecaprone polypropylene, yes.
Q. And you've used it?
A. I have used it, yes.
Q. And it has considerably larger pores than Prolene mesh, correct?
A. It has a larger pore than Prolene mesh, yes.
Q. And all of these products that are being discussed here, these are either pelvic floor prolapse products or stress urinary incontinence products, correct?
A. Well, Gynemesh Plus M and Prolift Plus M are for prolapse. TVT slings are for incontinence.
Q. And Prosima is for prolapse, correct?

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A. Prosima is for prolapse as well as Prolene and Gynemesh.
Q. That's what I'm saying, every one of the products listed on this exhibit are products for the treatment of either pelvic organ prolapse or stress urinary incontinence, correct?
A. On the column, on the side, under EWH&U, yes.
Q. And you would disagree with that document?
A. On what part would I disagree?
Q. That, describing TVT slings as being microporous?
A. Yeah, I do disagree with that.
Q. Do you agree that Gynemesh Plus M and Prolift Plus M is macroporous, do you agree with that portion?
A. They're all macroporous.
Q. You would put every one of these products in the macroporous category, not the three separate categories that Ethicon internally did, correct?
A. Yes, that's, they're all macroporous products.
Q. Even if Ethicon describes them as three different weights?

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A. Yeah, the, the reports for -- the definitions for microporous and macroporous are very clear.
Q. Now, do you know Joerg Holste?
A. No.
Q. Have you ever heard of him before?
A. No.
Q. I'm the first, me uttering his name is the first time you ever heard it?
A. Yes.
Q. Okay.
A. I may have heard his name from, or seen it, but I don't, maybe once, I don't know, I don't recall this, this person.
Q. Okay, did you know that you put down on your reliance list that you read his deposition and relied on it in forming your report in this case?
A. I read that over a year, a year ago, yes.
Q. Well, you just signed this last week, didn't you, sir?
A. Well, you just asked me if I knew him. I don't know him.
Q. I asked you do you know who he is. You don't even know who he is?
A. I don't know who he is.

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Q. Okay, that's fine. And three days ago you supplemented your reliance list, and Dr. Holste is listed as one of the depositions you read and relied on in forming your opinions, correct?
A. Yeah, I read it a very long time ago.
Q. Okay. But he's on your reliance list, correct?
A. He's on my reliance list, yes.
(Plaintiff's Exhibit No. 12 was marked for identification.)
BY MR. FREESE:
Q. Let me show you Exhibit 12 to your deposition, sir, and show you a question and answer that Dr. Holste was asked at his deposition, the deposition that you got on your reliance list. He says, the question is, quote, "And Prolene old-construction mesh at 100 to 110 grams per meter squared is considered a heavyweight mesh, correct?"
Answer: "Correct."
Do you see that?
A. Yes.
Q. And you disagree with Dr. Holste?
A. No, 110 grams per square meter, that's heavy.
Q. That's a heavyweight?

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A. That's the heaviest I've ever seen, by the way.
Q. Did you know that Prolene was 100 to 110 grams per meter squared? Did you know that was the weight of Prolene?
A. No, that's old-construction Prolene.
Q. That's old-construction Prolene. Do you know that's the same mesh that TVTs are made out of?
A. No, I don't know that.
Q. Okay, you don't believe that?
A. I don't believe that.
Q. Okay. But you would agree that if the mesh is 100 to 110 grams per meter squared, that's a heavyweight mesh under anybody's definition, correct?
A. That's the heaviest I've ever seen.
Q. Okay. And you think that's a different mesh than what's used in TVT?
A. Yes.
Q. And you've never seen, that you recall, this deposition testimony I just showed you, right?
MS. GALLAGHER: Object to form.
A. I, I read about his deposition, I read his, may have read his deposition once.
BY MR. FREESE:
Q. Which you said you relied on in your

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reliance materials, correct?
A. Right.
Q. This is the guy who you said you relied on, correct?
A. No, this is the guy that you're showing me a picture right now that you tell me that I have relied on.
Q. No, sir, I'm showing you your reliance list. Joerg Holste. You see that? Here's a nice picture of Dr. Holste. Deposition testimony of Dr. Holste taken July 29th, 2013. Do you see that?
A. Yes.
Q. Same guy, right?
A. Yes.
Q. Okay.
A. I don't know if that's the same guy.
Q. Well, if it's not, I'm sure Ms. Gallagher is going to let me know very quickly, but if that's the same guy, we can at least agree that you don't agree with Dr. Holste saying that Prolene mesh is heavyweight, but you agree that at 110 grams per meter squared is heavyweight mesh?
MS. GALLAGHER: Object to form.
A. Yes, that's the heaviest I've ever seen.
BY MR. FREESE:

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Q. Now, do you know who Brigette Hellhammer is?
A. No.
Q. Have you ever heard that name before?
A. I don't recall that one.
(Plaintiff's Exhibit No. 14 was marked for identification.)
BY MR. FREESE:
Q. All right. Let me show you what I've marked as Exhibit 14 to your deposition, sir.
MS. GALLAGHER: Did we skip 13?
MR. FREESE: I did. I'm going to come back to 13.
BY MR. FREESE:
Q. You see Dr. Hellhammer here? Do you see that, sir?
A. Okay, yeah, I see her name here. Brigette Hellhammer.
Q. And you testified that Prolene was, was a large-pore mesh, correct?
A. Yes.
Q. All right. And you see that in September, 2013, Dr. Hellhammer's deposition was taken, just like we're here taking yours, and she's under oath, and she was asked the question: "And you agree

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that Prolene mesh that was used in TVT was small-pore mesh, correct?" And what was her answer, sir?
A. She answered yes.
Q. And do you recall ever seeing this deposition question and answer before today?
A. No. No, I certainly do not recall this one specifically.
Q. Do you realize that she also appears on your reliance list?
A. Yes.
Q. That you relied specifically on her deposition that was taken on 9/11 and 9/12 of 2013. Do you see that?
A. Oh, she's in the whole list of those documents. I did not, I do not rely for my opinion on whatever she says.
Q. I'm not asking you that, sir. I'm asking you, you put on your reliance list that you read and relied on Dr. Hellhammer, and I've just shown you a question and answer where she said Prolene mesh was a small-pore mesh. Do you see that?
MS. GALLAGHER: Object to form.
A. But I disagree with her.
BY MR. FREESE:
Q. I understand that. That was my next

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question. You disagree with her, correct?
A. Yes, I do.
Q. Do you know who she is?
A. No.
Q. Do you know what her background is?
A. No.
Q. Do you know whether or not you're more familiar with the pore size of mesh than Dr. Hellhammer is?
A. I know what I know. I don't know what she knows.
Q. Do you know she's a German employee of Ethicon?
A. No.
Q. Did you know that Dr. Holste was a materials expert for Ethicon in Germany?
A. No, I don't, I don't know that.
Q. And you simply disagree with her conclusion, is that correct?
A. Yes.
Q. All right. Now, let me show you what I'm marking as Exhibit 13 to your deposition.
(Plaintiff's Exhibit No. 13 was marked for identification.)
BY MR. FREESE:

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Q. I think we went backwards. But, you see this article, sir?
A. Yes.
Q. The argument for lightweight polypropylene mesh in hernia repair?
A. I see this article, yes.
Q. By Dr. Cobb and Dr. Kercher and Dr. Heniford?
A. Yes.
Q. Have you seen this article before, sir?
A. I may have seen it. I can not remember.
Q. Did you realize it's on your reliance list?
A. It's probably on my reliance list, yes.
Q. Okay. And did you read it?
A. Yes, actually, I read that sometime ago, even before it was, it was a matter of litigation.
Q. Okay, turn to the second page. It says concept of lightweight mesh. Do you see that?
A. Yes.
Q. And you see that there's a table of polypropylene meshes with different densities?
A. Yes.
Q. And you see that Dr. Cobb has reported that Prolene mesh is 105 grams per meter squared?

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A. Yes.
Q. That's heavyweight mesh, is it not?
A. That is a heavyweight, yes.
Q. And you just described, you told me anything that would be 105 to 110 grams would be the heaviest mesh you can recall, correct?
A. A hundred ten is the largest that I have seen.
Q. And if we look at Prolene mesh, that is the mesh used in TVT, is it not?
A. The Prolene mesh are used on TVT may be lower than that.
Q. Well, do you have anything that says it is?
A. Yes, actually, yes, I think I have a paper that actually says that.
Q. Well, I'm showing you a paper that you relied on to put in your, your reliance list that says the weight of the Prolene mesh is 105 grams per meter squared. You have no reason to dispute that, do you?
A. Yeah, but this is a, this is a paper about hernia.
Q. It's dealing with Prolene mesh, sir. You understand that, do you not?
A. Yeah, I do understand that.

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Q. And it's reporting Prolene mesh at 105 grams per meter squared, correct?
A. Yes, it is reporting that.
Q. And you said it's dealing with hernia, but you cited it yourself in your own report, did you not?
A. It's not specifically for this hernias. I do not cite in this report for Jennifer Ramirez, I do not cite this specific report.
Q. Yes, you did. You don't think that you cited this article in your report?
A. Yeah, I want to see exactly where, where is it.
Q. I'm talking about in your reliance list.
A. Oh, okay, you're talking about reliance list, yes, it is in the reliance list.
Q. Okay, because you've given us a 100-page reliance list that says these are the materials that Jaime Sepulveda has relied on in forming my opinions, correct?
A. Yes, but --
MS. GALLAGHER: Form.
BY MR. FREESE:
Q. And that includes this article, does it not?

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A. Yes, but the definition of relied doesn't mean that I'm using it for my, for my, to, to substantiate my, my opinion. I, I do read papers that I exclude as I, as I'm reading them.
Q. You didn't exclude this paper from your reliance list, did you? You included it.
A. Yes, it's included in there, but it's not in my report.
Q. And, in fact, Prolene mesh is even heavier than Marlex, is it not?
A. Yes, it shows that.
Q. And you know what Marlex is, do you not?
A. I know Marlex, yes.
Q. It's polypropylene also, is it not?
A. Yes, but it's not a multifilament.
Q. You think Marlex is a multifilament?
A. Yes, it's just a multifilament.
Q. Okay, and what product is Marlex used in?
A. The pore size is a lot smaller because it's a multifilament.
Q. Okay, where did you get that from?
A. From what I have read.
Q. Okay, can you cite me any --
A. That's Mersilene.
Q. You think Marlex is Mersilene?

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A. Yes.
Q. Okay. Marlex is polypropylene, Dr. Sepulveda.
A. Yes, so, it's a Mersilene.
Q. And you think that, that Marlex is a multifilament?
A. Yes.
Q. And what is your support for that?
A. That I have read about Marlex before.
Q. Okay. Do you know that it's used in, in Boston Scientific and AMS slings?
A. I never used a Boston Scientific.
Q. You've used AMS slings before, have you not?
A. I used AMS slings, but they were not made of Marlex.
Q. Okay. Who do you think makes the polypropylene for AMS and Bard and Boston Scientific slings?
A. I don't know.
Q. You don't think it's Marlex, though?
A. No, it's not Marlex.
Q. And you see where it says the weight of Ultrapro is 28 grams per meter squared?
A. Yes.

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Q. And that is about one-quarter the weight of Prolene, is that correct?
A. That's about a quarter, yes, according to this table, yes.
Q. Now, Doctor, would you look at, down at the first column on the concept of lightweight mesh, you see it there?
A. Yes.
Q. See where it says Marlex?
A. Yes.
Q. Marlex, paren, C.R. Bard. Do you know who C.R. Bard is?
A. That's a company, yes.
Q. That makes slings, correct?
A. They, they do make slings.
Q. It says Marlex is a standard monofilament heavyweight polypropylene mesh. Do you see that?
A. Is a monofilament, yes.
Q. So, you want to retract your last answer about Marlex?
A. No, because it's a, with the pore size that it has, it's a, that's a multifilament.
Q. Well, according to the Cobb article, it's a standard monofilament. Do you disagree, then, that Marlex is a standard monofilament heavyweight

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polypropylene mesh?
A. Yes, the pore size in Marlex is a small, is a small size and it behaves like a multifilament. The weave, the weave -- I'm sorry, the knit is a multifilament.
Q. This article says it's a monofilament, not a multifilament. Do you see that?
A. That's what this article says.
Q. And you disagree with the Cobb article on that?
A. Yes, the fibers are too close.
Q. It goes on to say that it contains 95 grams per meter squared of polypropylene, is porous but has very small inter -- I always have a hard time pronouncing that.
A. Interstices.
Q. Would you tell us what that is, please?
A. It's the space in between the fibers.
Q. It says it's extremely strong. It says several comparable formulations of heavyweight polypropylene are available with a similar polypropylene content as Marlex, including Prolene, Ethicon, Inc., Somerville, New Jersey. Do you see that?
A. Yes, that's what it says, yes.

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Q. That's saying that, that from a weight standpoint, that Prolene and Marlex are both monofilament heavyweight meshes, correct?
A. Marlex is lighter, but the configuration of Marlex makes it as a multifilament.
Q. That's not my question. According to Dr. Cobb, both Prolene and Marlex are heavyweight polypropylene meshes, correct?
A. According to, to Dr. Cobb, it's, it's porous but has very small interstices, which is what I've been referring to.
Q. And it says several comparable formulations of heavyweight polypropylene are available with similar polypropylene content as Marlex, including Prolene, correct?
A. Yes, including Prolene.
Q. Do you agree or disagree with that statement?
A. Well, it says that there are several, several heavyweights. That's what he is explaining.
Q. He says Marlex and Prolene are both heavyweight polypropylene mesh.
A. That's what he says, that it's heavyweight, yes.
Q. And you disagree with that?

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A. Yeah, the, the mesh in use of slings is not a heavyweight mesh.
Q. Well, if it's 105 grams per meter squared, you would agree that it's heavyweight, right?
A. Yes, that's heavy.
Q. All right, and if I proved to you at trial that Prolene mesh used in TVT and TVTO and TVT Abbrevo and TVT Secur is 105 grams per meter squared, we would all agree then that that's heavyweight mesh?
A. At 105 or 110, what I have shown you, you have shown me, I will have no other choice but to agree with you.
Q. Thank you, sir. Dr. Sepulveda, if you would look at page 18 of your report. You see where, in the first full paragraph, you say, when placed per the IFU, the risk of deformation of the tape is reduced?
A. When placed per the IFU, the risk of deformation of the tape is reduced.
Q. You see that?
A. Yes.
Q. And my only question is, is reduced compared to what?
A. It's to, to the deformation that you would have if you put it without plastic sheaths.

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Q. Okay, you're saying the use of the plastic sheath reduces the deformation of the mesh when it's being implanted?
A. Yes, and the, when the IFU explains that there is, not to put it too tight, that's how you prevent deformation.
Q. Deformation of the, of the mesh is an unwanted result, is it not?
A. No, when I talk about deformation, I'm talking about biomechanical deformation. Deformation in biomechanics is different from deformation that we see normally, and deformation has to do with the change on the dimensions of the tape.
Q. I'm not, I'm not quibbling with you about that, but we can agree that deformation generally is an unwanted result of the mesh, either mechanically or in vivo, or any process you don't want the mesh to deform, correct?
A. Well, in any viscoelastic that is used will have a degree of deformation, which is that it changes in shape. Any, any viscoelastic, any viscoelastic substance will go through deformation, your skin, your ligaments, and any implant that you may place.
Q. Look at page 19, sir. The last

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paragraph, where it starts with complications.
A. Yes.
Q. You see where it says the transobturator approach showed a higher frequency of early postoperative pain as the insertion needle went through the superficial muscles of the leg? Do you see that?
A. Yes.
Q. What are you defining as superficial muscles of the leg?
A. Specifically, the adductor magnus.
Q. The adductor magnus muscles?
A. Yes.
Q. Okay. And you go on, this complication is most often transient and managed with medication. What does it mean, most often transient?
A. It's of short duration.
Q. Okay. So, more than half the time it's of short duration?
A. Yes.
Q. All right, and it could also be a long-term pain and a long-term complication, can it not?
A. I think that was defined as something that is extremely rare.
Q. And how do you define extremely rare?

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A. It's when, when you look at the, at the leg pain in the cohorts that are five years and seven years, there's, there's a very low rate of long-term pain. Actually, it's not, it's not described in many of these papers, it's not described.

Q. Look on page 20. You see the paragraph that begins it became evident that specialized knowledge of the obturator site and the anatomy and relationship of the vascular, muscular and nerve studies were required for a reproducible and safe obturator procedure, do you see that?

A. Yes.

Q. Where is that in the IFU? Where does it say that, that you need special knowledge of the anatomy in order to safely implant an obturator device?

A. It's part, knowing the anatomy is part of what is required from a physician as stated on the IFU. It's physicians that are familiarized with continence procedures.

Q. But you're saying specialized knowledge over and above the average physician is necessary?

A. No, specialized knowledge is knowing exactly about the obturator space.

Q. But specialized knowledge compared to who?

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A. Compared to what you do normally. I'm going to explain that.

Q. What I want to know is, are you talking about special knowledge within a subgroup of doctors, or simply you have to have more anatomical knowledge than, say, a court reporter or a lawyer?

A. No, you, you need, even if do you continence procedures, you're going to, you're needing to know the anatomy of the obturator space.

Q. Is it anywhere in the IFU that you have to have specialized knowledge of the anatomy in order to safely reproduce an obturator procedure?

A. It just says that physicians should be trained on the procedure.

Q. Okay. And it says that the, the, the obturator neurovascular bundle 1.2 to 1.5 centimeters for TVTO, that's the distance between where a properly-placed TVTO should go in the obturator nerves?

A. That's what has been, has been measured.

Q. Okay. So, in other words, if a TVTO is properly placed, it should be 1.2 to 1.5 centimeters from the obturator nerve bundle?

A. Yes, there's a safe area for placement of a transobturator sling that is about 2.5 centimeters, 1.5 to 2.5 centimeters from the obturator neurovascular bundle.

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Q. How far is a properly-placed TVTO from a pudendal nerve bundle?

A. It's at least four centimeters.

Q. You go on to say, on the next page, the proximity to the obturator neurovascular bundle was most frequently a failure to orient the device from 45 degrees to 90 degrees as specified by the IFU.

A. Yeah, there are three, three factors that have been validated as the variations in the placement of a transobturator sling from the inside out. The first factor is the dorsal lithotomy position, which is addressed by the IFU. The second factor is the insertion, or the depth of the insertion of the needle in the periurethral space, and the, the third factor is a full rotation of the wrist with rotation from 45 to 90 degrees when the needle is exteriorized. Those three factors determine how close the tape is going to, is going to be in relation to the neurovascular bundle.

Q. All right, and if it's not done that way, then you can get an obturator nerve injury?

A. Yes, if you, if you actually dissect a cadaver and you insert it wrong to see where you get out, you can, you can get there.

Q. You say you can get there, you can get

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there and you can damage or injure an obturator nerve?

A. You can, you can injure an obturator nerve as has been shown in some, some reports.

Q. Now, Doctor, you discussed --

A. And when I say as it has been shown in some reports is that anatomically, it has been described that when you don't insert the device properly, you can injure the neurovascular bundle.

Q. All right. Have you ever seen a report of an obturator nerve injury from the explant of a TVT?

A. No.

Q. As you sit here today, there's no literature that we can find that, that you've seen that's been reported where any patient has suffered an obturator nerve injury from the revision or removal of a mesh sling?

A. No, I have not seen an obturator nerve injury from the removal of a, a sling.

Q. And what about the pudendal nerve injury, have you ever seen a report of a patient getting a pudendal nerve injury from the removal or revision of a sling?

A. I have not seen that, that report.

Q. Ever?

A. It has not been published.

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Q. Have you in your practice come across that?
A. No, I have not seen that in my practice.
Q. You say in 2013 that the -- well, strike that.
You document 2008, 2011, 2013 FDA Public Health Notifications regarding synthetic mesh?
A. Well, for this one it's the 2008 because the sling wasn't implanted in 2010 in this case.
Q. Right. So, the only, the only FDA notice that Dr. Reyes could have been aware of is the 2008, correct?
A. That is correct.
Q. Because the 2011, 2013, hadn't even come out yet?
A. That's correct.
Q. All right. Doctor, you say on page 22 of your report that the TVTO device is accompanied by an IFU and that you have reviewed the TVTO IFU. Correct?
A. Please repeat that.
Q. Yeah, I was reading that you have reviewed the TVTO IFU and you find it adequate and complete for its use in the operating room?
A. Yes, I did.
Q. And you said I understand that the IFU is

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not a comprehensive guide for surgical treatment of SUI. Do you see that?
A. Yes, that's the way it's stated.
Q. Do you agree that a doctor implanting a TVTO should be allowed to rely solely upon the IFU to ascertain what complications if any may result from the use of that device in counseling his patient?
A. I think that the IFU needs to speak about the specifics of the implant, but the continence procedure, the risk of the continence procedure pertains to the formation and the training of the doctor.
Q. Well, that's not my question. My question is, do you agree that a doctor should be able to rely solely on the IFU and nothing else in educating himself about the complications that could result from the use of a device?
A. No.
Q. Is that reasonable or not?
A. No, they should not rely just on the IFU. There's a wealth of data out there about the indications and the use of the device.
Q. Do you agree with me that in order for Ethicon to do its best to make sure that a patient is appropriately counseled, that Ethicon needs to provide

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the known risks and adverse events in the IFU so that information will be available to the doctor to pass on to patient, do you agree with that?
A. I expect Ethicon to state the risks inherently associated to the mesh.
Q. And do you agree with me that if Ethicon fails to provide the necessary information regarding the risks and adverse events and complications to the doctor, there's a risk at that point that the patient cannot be properly counseled because the information has not been provided to the doctor, do you agree with that statement?
A. The IFU is intended to educate the physician on the performance of the procedure. Part of it is going to be the complications from the device that remains on the patient.
Q. Listen to my question. Do you agree with me that if Ethicon fails to provide the necessary information regarding the risks and adverse events and complications to the doctor, there's a risk at that point that the patient cannot be properly counseled?
MS. GALLAGHER: Object to form.
BY MR. FREESE:
Q. Do you agree with that statement or not?
A. We don't, we don't use the IFU for

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patient counseling.
Q. Well --
A. So I disagree, I disagree with the statement that if it's not placed on the IFU, I expect the IFU to address the complications that have to do with the tape, it should give me direction on how to use the device, but I, I don't expect them to give me the benchmark for patient education.
Q. And, Doctor, that question didn't involve the IFU.
A. Okay.
Q. So, you have to listen to my question. I'm just asking you if you agree with this statement, that if Ethicon fails to provide the necessary information regarding the risks and adverse events of complications to a doctor, there's a risk at that point that the patient cannot be properly counseled because the information has not been provided to the doctor. Do you agree with that?
MS. GALLAGHER: Object to form.
A. No, I disagrees with that because the only source of information for a physician before they counsel a patient is not Ethicon.
BY MR. FREESE:
Q. And do you agree or disagree that if

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Ethicon fails, if it happens that Ethicon fails to provide material information about the risks of, for example, a TVT or any medical device, to the physician, if it actually happens and the doctor just relies on the IFU regarding the risks and doesn't tell a patient a risk that the doctor wasn't told about, the patient would not have been properly counseled?

MS. GALLAGHER: Object to form.

BY MR. FREESE:

Q. Do you agree or disagree with that?

A. I agree that if the doctor relies just on the IFU, they will not be able to provide enough counseling to the patient.

Q. Do you know Dr. Hinoul?

A. Yes.

Q. He's a medical affairs director at Ethicon, is he not?

A. Yes.

Q. He's a urogynecologist, is he not?

A. He is.

Q. He's trained the same way you're trained, correct?

A. I don't know if it was the same way, but I know he's a urogynecologist.

Q. And his job is to make sure that, from a

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medical standpoint, that doctors are getting properly warned of the risks of using TVT, correct?

MS. GALLAGHER: Object to form.

A. I'm not aware of his job description.

BY MR. FREESE:

Q. When is the last time you talked to him?

A. At an AUGS meeting.

Q. Okay. You actually reviewed and logged his deposition in this case, did you not?

A. Yes, I did see one of his depositions.

Q. I want to show you page 2007 and 2008 of his deposition that was given January 14th, 2014, okay? And you see where it says, quote, "In order for Ethicon to do its best to make sure that a patient is appropriately counseled, Ethicon needs to provide the known risks and adverse events in the IFU so that information will be available to the doctor to pass on to the patient. Right?" And he says, "Absolutely." Do you see that?

A. Yes.

Q. Do you agree with his answer?

A. If Ethicon is the only source, but I think in the context in which he was asked, from what I see from that answer, absolutely, is, is Ethicon going to provide that information, and he's testifying as a

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medical director for Ethicon.

Q. Yes.

A. So, so, the question is, is that the only thing the doctor relies on, do I agree to that?

Q. No, I'm asking do you agree with Dr. Hinoul's answer, absolutely, to the question that was just asked; do you agree with his answer?

A. Yeah. In order for Ethicon to do its best to make sure that a patient is properly counseled, Ethicon needs to provide the known risks and events in the IFU so that information will be available to a doctor to pass on to the patient. Yes, that's --

Q. You agree with that?

A. If they're aware, if they're aware of any complications, that will be, that's, Ethicon will have to transmit it for the doctor to be aware.

Q. If Ethicon is aware of a complication, they have to transmit it to the doctor?

MS. GALLAGHER: Object to form.

A. I would agree that that's the only way that the doctor could know.

BY MR. FREESE:

Q. All right. Okay. And, he goes on to say, "And, therefore, if Ethicon fails to provide the necessary information regarding risks and adverse

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events and complications to the doctor, there's a risk at that point that the patient cannot be properly counseled because the information has not been provided to the doctor, correct?" And Dr. Hinoul's answer is, "That is correct." Do you see that?

A. Yes, but I disagree with him because I don't --

Q. So, let me, first of all, did I read the question and answer correctly?

A. Yes, sir.

Q. Do you agree with Dr. Hinoul?

A. No, I don't agree that Ethicon is the only source. In his answer, he's saying that, I mean, there's this long, long question, and then he says he agrees. The substance of it is Ethicon is not the only source that I'm going to consider counseling my patients.

Q. It doesn't say only source. It says if Ethicon fails to provide the necessary information regarding risks and adverse events and complications. to the doctor, there's a risk at that point that the patient cannot be properly counseled because the information has not been provided to the doctor, correct? And Dr. Hinoul says that is correct, and you disagree with that?

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A. Okay, the specific question there on what can be inferred from the question, so I'm going to answer to you the best, the best way I can answer is, if Ethicon does not disclose it, if there's no disclosure, there's no way for the physician to know it unless it has to do with the procedure itself. Now, we don't rely just on the IFU and we don't just rely on Ethicon to tell us about the, the procedure.

Q. I'm going to get there, Doctor. I just want to know whether or not you agree or disagree with what Dr. Hinoul just said there.

MS. GALLAGHER: Objection to form. He's explaining to you why he can't say agree or disagree.

MR. FREESE: Well, I'm not sure he is --

MR. GOSS: I think the form is fine.

MR. FREESE: Just form, that's all we need.

BY MR. FREESE:

Q. Do you understand my question, Dr. Sepulveda? I read you the question on lines 1 through 7 of page 1208 and the answer on line 8. All I want to know is, do you agree with Dr. Hinoul or do you disagree with Dr. Hinoul?

MS. GALLAGHER: Objection to form.

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A. I will have to disagree with that with Dr. Hinoul, because it implies that the only source that you have is Ethicon, and that's not the only source that I have.

BY MR. FREESE:

Q. And you understand he was speaking on behalf of Ethicon in his deposition?

MS. GALLAGHER: Objection to form.

A. Yes, he's the medical director for Ethicon.

BY MR. FREESE:

Q. And the next question, "And, in fact, if Ethicon fails, if it happens that Ethicon fails to provide material information about the risks, for example, of the TVT or any medical device, to the physician, if that actually happens and the doctor just relies on the IFU regarding the risks and doesn't tell the patient the risks that the doctor wasn't told about, the patient would not have been properly counseled, correct?" His answer is, "I am in full agreement, the surgeon should be able to rely solely on the IFU, absolutely." Do you see that?

A. For the patient counseling, solely on the IFU?

Q. Yes, sir.

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A. I would disagree on that, no.

Q. Even though Dr. Hinoul says absolutely, a doctor should be able to rely solely on the IFU, you disagree with Dr. Hinoul?

MS. GALLAGHER: Object to form.

BY MR. FREESE:

Q. Correct?

A. Yes, I don't think you're going to find any physician that would agree with just relying solely on the IFU.

Q. Let me ask you this, Dr. Sepulveda. Who knows more about the complications of Ethicon's products, you or the medical affairs doctor at Ethicon?

MS. GALLAGHER: Object to form.

A. I think I'm in a privileged position to know what kind of complications patients have when you follow the IFU.

BY MR. FREESE:

Q. I'm asking you, who knows more about the complications related to TVTs, Dr. Hinoul or you?

MS. GALLAGHER: Object to form.

A. I do.

BY MR. FREESE:

Q. Okay. So the jury should conclude that Jaime Sepulveda knows more than the urogynecologist

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hired by Ethicon to be its worldwide medical affairs doctor, you know more than he does?

MS. GALLAGHER: Object to form.

A. Yes, I have implanted more TVTs than he has.

BY MR. FREESE:

Q. Who has seen more internal documents about the complications of the use of TVT, you or Dr. Hinoul?

A. Dr. Hinoul sees more internal documents.

Q. It's not your job to write the IFUs for TVT, is it, or TVTO?

A. No, it's not, I don't write the IFUs.

Q. You understand that all of the warnings and complications that appear in a TVTO IFU are written by the medical affairs people at Ethicon, correct?

MS. GALLAGHER: Object to form.

A. That's what I would expect to write it, yes.

BY MR. FREESE:

Q. People like Dr. Hinoul?

A. Yes.

Q. He's the one in charge of making sure it's accurate and full and gives the doctors all the information they need regarding complications of the

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procedure, correct?
MS. GALLAGHER: Object to form.
A. He writes the IFU.
BY MR. FREESE:
Q. And that's his job 24/7, correct?
MS. GALLAGHER: Object to form.
A. I don't know if it's 24/7. He writes the IFU.
BY MR. FREESE:
Q. But that's his job, that's what a medical affairs director does, correct?
A. I'm not familiar with their duties, but I think that he has an input on the IFU.
Q. And yet, you would substitute your judgment for his on what a doctor should rely or not rely on out of the IFU?
A. No, I did not testify on that. I said --
Q. I'm asking you, is it your opinion that --
MS. GALLAGHER: Don't cut him off, please.
BY MR. FREESE:
Q. Sorry. Go ahead.
A. What I testified is that I have placed more TVTOs, I've done more follow up on these patients

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than he has. I use the product, I would know about any problems it would have. I would not have continued to use the polypropylene mesh for midurethral slings to this day if I would have seen or I would have had any problems.
MR. FREESE: Move to strike.
BY MR. FREESE:
Q. That's not my question, sir. My question is simply, Doctor, you would substitute your judgment on what an implanting physician should rely on in the IFU over Dr. Hinoul's judgment about what a doctor should rely on or can rely on from the IFU, correct?
MS. GALLAGHER: Object to form.
A. No, Dr. Hinoul does the, he writes the IFU. Dr. Hinoul is in a, in a position to see skewed data of how the procedure performs, because I can tell you that Dr. Hinoul do not get a phone call or a report of how many patients have done better and how many patients have been improved in their quality of life. He gets --
BY MR. FREESE:
Q. How do you know that?
A. He gets a report about complications.
Q. How do you know that? How do you know what he gets?

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A. I can tell you that any of my 2,000 patients have called him and say, Piet Hinoul, I'm doing great.
Q. Let's do this, Doctor, can you we agree you don't know what, you have no personal knowledge of what Dr. Hinoul knows or he doesn't know?
MS. GALLAGHER: Object to form.
A. No, I already testified, I'm not aware of his job description.
BY MR. FREESE:
Q. And you have no idea what he knows or what he doesn't know, do you?
A. Actually, I --
Q. My question is, what personal knowledge do you have of what Piet Hinoul knows or doesn't know about complications of TVT slings?
A. I do not know. I just, I do not know that. I just --
Q. And how many --
MS. GALLAGHER: Please, let him finish his answer.
MR. FREESE: Because he's now off, not responding to my question anymore. He's answered my question, now he editorializing. So, I mean, as long as I can charge the time

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back to you, I don't mind, but he can't sit here and read out of a telephone book, either. So, if it's not responsive to my question, we're wasting time. He's answered my question. If you want to ask him a question on redirect, that's fine.
BY MR. FREESE:
Q. My question to you is you have no clue how many slings Dr. Hinoul has implanted, do you?
A. Yeah, actually, I asked him.
Q. And what was his answer?
A. I, I, I probably remember that it was none here in the United States.
Q. I didn't ask you that. How many slings has Dr. Hinoul implanted in his life?
A. I think in my conversation with him at some point, I asked him if he could, if he could just come to clinical practice on this, on, on, on the United States, and he told me no, that he is a medical director.
Q. Dr. Sepulveda, I have no idea what you just said. My question is just simply --
A. I agree that I ramble. I agree with you on that.
Q. Sir, I have a great deal of respect for

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you, let's try not to ramble. My question is simply, do you know how many slings Dr. Hinoul has ever implanted in his life?

A. No, Mr. Freese, I don't know how many slings he has implanted.

Q. And do you know how many slings he has taken out in his life?

A. No.

Q. Do you know how many peer-reviewed articles he's written about slings?

A. No, I'm only familiar with his articles on the anatomy of TVTO.

Q. You know he's written at length on TVT, correct?

A. He, for this case, I actually relied on one specific article that he wrote about the anatomy.

Q. My question is you understand that Dr. Hinoul is published in peer-review articles, correct, on TVTs?

A. Yes.

Q. You, sir, have published zero peer-review articles on TVT slings, correct?

A. Yes.

Q. Okay. And you've done 2 to 3,000 sling procedures, correct?

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A. Yes.

Q. And you've only seen two or three complications in your entire 2 to 3,000?

A. Yes.

Q. Do you know how many complications Dr. Hinoul has seen?

A. In his line of work, probably has seen more than three.

Q. And, so, you've seen three out of 3,000, you have no idea how many he's seen, yet you feel comfortable saying you know more about complications from slings and what doctors need to know than he does?

A. No, I say I know more about outcomes. I could say, I could say that I know more about outcomes.

Q. You know about three complications out of 3,000, he may know way more than that. Yet you want to say that your information is superior to his?

MS. GALLAGHER: Object to form.

BY MR. FREESE:

Q. I mean, you realize Dr. Hinoul is responsible --

A. I still have to answer your question.

Q. I'm sorry. Go ahead.

A. My, my information, my information is on the, on the, on my clinical experience and my

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information is based on my, on dissection of multiple specimens, on the communications that I've had with my peers, and on the, on the, on what's published, although it is true that I have not published on TVT, I am in the forefront of providing patient care, so I know how this product performs.

MR. FREESE: Move to strike, non-responsive.

BY MR. FREESE:

Q. Doctor, you have no personal knowledge of how many doctors just like you that Dr. Hinoul talks to every day in his job?

A. I don't know who he talks to in his job.

Q. He talks to you, right?

A. No, we, we don't talk as part of his job. We, the last time we spoke we were sitting on a meeting enjoying the presentations of the scientific meeting.

Q. So, you were not talking about business with Ethicon with Dr. Hinoul?

A. No, I don't, I don't talk about those things. We have, we have other subjects that we speak about.

Q. You understand Dr. Hinoul has access to all the internal information available at Ethicon, correct?

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A. Yes.

Q. You do not, do you?

A. I do not.

Q. In fact, all you have available to you, Dr. Sepulveda, is what the lawyers for Ethicon want to show you, correct?

MS. GALLAGHER: Object to form.

A. In terms of the company documents, yes.

BY MR. FREESE:

Q. Okay. So, the company documents, let's define that, company documents about complications and the frequency of complications, those type of documents within Ethicon you don't have access to, do you?

A. No, I do not have access to that.

Q. Dr. Hinoul does, does he not?

A. I think he does.

Q. He has to. He's the medical affairs director.

A. He's the medical director for Ethicon.

Q. Real quick, Dr. Sepulveda, you've never measured the pore size of the TVT sling, have you?

A. Yes.

Q. Yes, you have never measured it?

A. Yes, I have measured it.

Q. Okay, when did you measure it?

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A. I put it together actually under the microscope at the pathology at South Miami Hospital, and I look at it and I measure it and then I confirmed what it was. Not only that, the pore size, but also the pore sizes with, with Prolift Plus M.
Q. The Ultrapro?
A. Prolift Plus M.
Q. Ultrapro?
A. It could be Ultrapro, but I did not take it as Ultrapro.
Q. Okay. What was the largest dimension of the pore?
A. On which one?
Q. On Prolene.
A. On the Prolene used for TVT was 1,200.
Q. Okay. And what was -- but that's not symmetrical, is it?
A. No, because of the knit, because of the way it's knitted, it could be 1,200, but it's never less than a thousand on each side.
Q. It's never less than a thousand and at its greater point it's 1,200?
A. Yes.
Q. 1,200 microns?
A. Microns.

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Q. And what did you use to measure the microns?
A. There's a little caliber on the microscope.
Q. When did you do this?
A. Years so.
Q. Okay. It's not in your report anywhere.
A. No.
Q. Okay, why didn't you put it in the report?
A. I didn't think it was relevant because the pore size have been well established by other publications.
Q. Did you record this somewhere when you did it?
A. No, I did not record that.
Q. Why did you measure the pore size?
A. Because I like to become familiarized with what I implant in my patients.
Q. What is the basis of your opinion that a TVTO made out of Ultrapro is not a safer alternative than a TVTO made out of Prolene?
A. There's a few areas on that. Number one is biomechanically, the TVT made of Ultrapro will not behave in the same way that a TVT made of Prolene.

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Q. Let me stop you and do it one at a time, okay? What is your basis for saying biomechanically they will not operate the same?
A. Well, they're two different types of material.
Q. Let me ask a better question. Have you seen any internal documents from Ethicon saying that they will act differently biomechanically?
A. No, I have not seen any internal documents. I have not read any internal documents.
Q. If there are internal documents that say they would behave similarly biomechanically, would you have liked to have seen these documents?
A. Either similarly or separate, but that's just the first part of my answer.
Q. I understand. We're taking them one at a time. So you've seen no document that says it would, that an Ultrapro TVTO sling would operate differently than one made for a POP, correct?
A. They're two different, those are two different applications.
Q. Okay, and you've never seen a single internal document making that comparison, correct?
A. No, I have not seen that comparison.
Q. And whether or not Ethicon concluded

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internally that it would be suitable to use Ultrapro in a TVTO application?
MS. GALLAGHER: Object to form.
A. I have not seen, I have not that on internal documents from Ethicon.
BY MR. FREESE:
Q. So your opinion is, I'm Dr. Sepulveda and because they're two different applications my opinion is they would behave differently?
MS. GALLAGHER: Object to form.
A. Yes, biomechanically, they would behave differently. It's not that they would say that to me.
BY MR. FREESE:
Q. And it's so because Jaime Sepulveda says it's so.
A. No, that's not exactly the case. That brings me to the --
Q. Hold on, we'll stay on this for a second. What is your basis other than it's my opinion that they would behave differently biomechanically?
A. By my biomechanical knowledge.
Q. Okay. Have you conducted any biomechanical testing of Prolene mesh versus Ultrapro mesh?
A. No, I have not conducted that test.

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Q. Okay. All right, what's your second basis for saying that Ultrapro would not be suitable?
A. There was, the way they behave, in my, when you're using it in the operating room, the way they handle, they're different.
Q. I understand that's your opinion, but you've done no bench testing on that, correct?
A. There's no bench testing on it.
Q. You've done no tensile testing, correct?
A. I have not done any of the bench testing that would be required to make that conclusion.
Q. You've done no cadaveric testing on Ultrapro as a sling versus Prolene, correct?
A. No, I have not done that test.
Q. And have you reviewed any of Ethicon's internal cadaveric testing?
A. No.
Q. Do you know whether or not actually Ethicon even tested Ultrapro in a sling application in cadavers?
A. No, I'm not aware of their testing.
Q. So they didn't show you the results of any cadaver testing for the use of Ultrapro as a sling internally, correct?
A. I can not say, I can not under oath say

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that I'm aware of specific testing or, or experiment that has been done.
Q. On anything, bench, cadaver, any kind of application?
A. No, I'm not aware of that.
Q. All right, what was the next reason, other than biomechanical, why you said that Ultrapro would not be suitable as a sling?
MS. GALLAGHER: Object to form.
A. The next reason is that there have been no clinical studies --
MR. FREESE: Stop for a second. What's the objection? I want to cure it.
MS. GALLAGHER: Because it's as a safer alternative design, that's the question you're asking him.
MR. FREESE: No, he told me that he had three reasons why Ultrapro would not be suitable as a, to be used as a TVTO.
MS. GALLAGHER: As a safer alternative design is what you're questioning him about. That's what he's answering.
MR. FREESE: Yes.
MS. GALLAGHER: Okay.
MR. FREESE: So, will you withdraw your

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form objection?
MS. GALLAGHER: No, because you're asking him about -- I thought the question had safety in it and suitability. He's talking about safer alternative design. That's a different analysis. That's my objection.
MR. FREESE: Okay.
BY MR. FREESE:
Q. Let me clarify. You're answering, Dr. Sepulveda, why Ultrapro would not be suitable or a safer alternative than Prolene for use in a sling application, correct? That's what you're answering?
A. In the sling application, yes.
Q. And you told me biomechanically, you didn't think it would operate the same?
A. That's correct.
Q. All right, what's your next reason?
A. The second is that we already have a device in place that has been tested extensively clinically. So, whatever, whatever evidence is, comes in has to be stronger than the evidence that we have on TVT.
Q. All right. Now, the only, you say that there's not demonstrating empirical evidence because you haven't seen any, you don't know if it's been done

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or not, you just haven't seen any, right?
A. Yes, there's, there has been no presentations that I heard on conference, there has been no texts that I have read, there has been no scientific randomized control trials, not even a cohort study that shows the use of a hybrid or partially absorbable sling.
Q. So, basically, then, that would be just the same as TVTO, wouldn't it? There were no randomized control studies, there were no cohorts, any of that done before TVTO was launched, correct?
A. No, that mischaracterizes my testimony on the basis that they're different, they're two different implants. The implant used on TVTO was the same implant that was used on TVT. The implant that would be used on Ultrapro is not the same as the implant that would be used on TVTO.
Q. Well, it's the same implant that was used in Prolift, was it not?
A. They are different applications. One is --
Q. They're both pelvic surgeries, are they not?
A. Well, they're different applications. One is urinary incontinence, the other one is prolapse.

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Q. Okay, so, you said that there was no empirical science, and that is because you haven't seen any, you don't know if there is empirical data within Ethicon because you haven't seen that, but you're simply saying you have not seen a published empirical data comparing an Ultrapro as a sling versus a Prolene, correct?

MS. GALLAGHER: Object to form.

A. There's no clinical evidence that shows that using a partially-absorbable sling is superior to the sling that we have used.

BY MR. FREESE:

Q. Okay, any other reason?

A. Yeah, the third reason is the consensus from the societies.

Q. Well, what has the society said about using Ultrapro as a sling?

A. I trust that the societies will come up with, with recommendations specifically on the use of the established clinical standard for the treatment of incontinence.

Q. Should I interpret that to mean that the relevant clinical societies have not commented one way or the other about the use of Ultrapro as a sling?

A. Actually, they have commented that

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specifically the use of monofilament polypropylene is the clinical standard on the case, on the treatment of urinary stress incontinence.

Q. I understand that. I'm asking -- my question is different, that no society has said that, that use of Ultrapro as a mesh sling would not be safer than the current design?

A. They have not recommended it, and they have not said that it's safer.

Q. So that's not really a reason because they haven't said one way or the other, correct?

A. As surgeons, we also follow the recommendations of the societies.

Q. I know, but the society has made no assertion one way or the other, so there's nothing to follow.

A. I'm not saying the society, I'm saying the societies, the clinical societies.

Q. I understand, you're talking about AUGS and ACOG and --

A. Right.

Q. And they have just not spoken to it, correct?

A. That's correct.

Q. Okay, so that's not a reason for it or a

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reason against it. It's silent.

MS. GALLAGHER: Object to form.

A. They have no evidence to speak one way or the other.

The fourth reason is that the FDA, the panel on the FDA on the executive summary did not offer that even as an alternative.

MS. GALLAGHER: We have lunch. Do you want to break?

MR. FREESE: Sure.

(A lunch break was taken from 1:17 p.m. to 1:29 p.m.)

BY MR. FREESE:

Q. Dr. Sepulveda, I want you to turn to the Roman numeral IV, expert opinion overview in your report. I think it may be 55 on your version. It's page 54 on mine, I think that's just because of the way it's printed. Tell me when you get there.

A. Yeah, I'm here.

Q. Just so I understand, you give opinions throughout your report, but is section IV intended to sort of like summarize the important opinions that you intend to give in a case?

A. Yes.

Q. Okay, I realize you give more than what's

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in section IV and we'll go back and visit about some of that, but this expert opinion overview is sort of a summary of the opinions that you're going to give?

A. Yes.

Q. Okay. All right. The fact that Jennifer had UTIs, vaginal infections before the implantation of the TVTO, is the significance of that is that you're saying there's not a cause and effect with the mesh because she was suffering from these incidents earlier?

A. Right, that's, these are two very frequent conditions in women.

Q. And, so, the fact that she had urinary tract infections before she had mesh is your opinion that the mesh didn't cause any UTIs?

A. That's correct.

Q. Okay. Mesh can cause UTIs, can it not?

A. If you have a mesh that actually obstructs the urethra, it can cause urinary tract infections.

Q. And you said that she had reported dyspareunia before the implantation of the mesh, correct?

A. Yes.

Q. Do you know how long before that and how many times in her life she ever reported dyspareunia?

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A. I know of at least one instance in which she reported.
Q. And I do, too, that's all I can find. So, can we agree that you and I can only find one reported incident of dyspareunia prior to the implantation of the mesh?
A. Yeah, we can agree on that.
Q. And that fact is the basis for your opinion that the mesh didn't cause dyspareunia because she reported it at one time previous in her life?
MS. GALLAGHER: Object to form.
A. And, again, there's, that's not the only reason why I say that she may have dyspareunia, and there are other conditions within the surgery itself, within her clinical course itself that could predispose to dyspareunia.
BY MR. FREESE:
Q. And we'll talk about those, but having it before the implant one time is part of your opinion why it's not being caused by the mesh now?
A. That's part of it.
Q. Okay. You said that she had two previous devices implanted, an IUD and an Essure.
A. Yes.
Q. And had complications with the IUD which

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led to its removal.
A. Yes.
Q. Okay, what's the significance of that?
A. Any time that you may have any implant, there is a risk to have it removed.
Q. Okay. So, you're saying the fact that she had an IUD that got a complication and had to be removed, why is that relevant to your opinion in this case?
A. There's an understanding from, from Mrs. Ramirez that whenever anything can be implanted, it may need to be removed.
Q. The Essure, what is the relevance of that in your opinions?
A. Well, Essure is an implant that is permanent.
Q. Okay.
A. It either stays there or it absorbs, and, again, I'm in a much better position to give testimony about a sling, but in general, what I know about Essure is just about what I read about the product. I have to, I want to be accurate and say that I have not implanted Essure, but it's just another implant.
Q. Okay, and just so I won't waste any time on it, the injuries and problems and harms that

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Jennifer alleges in this lawsuit are not in any way impacted or caused by the Essure, in your opinion?
A. I don't see a relationship between the Essure and any claims that I have read.
Q. Okay. So, we can take Essure off the table as being relevant to anything that's going on with Jennifer today?
A. On her symptoms that she's complaining of now, yes.
Q. And that would be true of her IUD also?
A. That's correct.
Q. Okay. Was her only risk factor for SUI three vaginal deliveries?
A. That's the largest risk factor actually, yes.
Q. And that's the only one that you identified in your report, is that correct?
A. Well, there's no way to know by family history based on the medical records, which is also a very, a very strong risk factor, and three vaginal deliveries and an early age delivery.
Q. Okay, so, three deliveries, early age, and possibly family but you don't know?
A. Exactly.
Q. You're not going to give an opinion about

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what all doctors know, are you?
A. I don't understand the question.
Q. Well, I mean, you say that, that doctors from their med school, residency, fellowship, that risks of incontinence pelvic surgery are all well known to doctors. You're not here to give an opinion what all doctors know, are you?
A. No, I can not testify what all doctors know, but I can do, say what's required from us in the, in the guidance to get us credentialed and be board certified.
Q. You know what you were taught in medical school, correct?
A. Yes.
Q. And you know what you were taught in your residency?
A. Yes.
Q. You don't know what everyone else was taught in medical school or their residency?
A. I don't know what they were taught. I know about the requirements to pass the examinations.
Q. And you don't intend on offering any opinions about what doctors know about pelvic surgery or complications from pelvic surgery?
A. I can offer an opinion about the, what

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we, the complications that are for each surgery.
Q. Based on your personal experience?
A. And also on, on what has been reported.
Q. All right. You note in here that you trained Dr. Reyes.
A. He came, he came to, to see me to do surgery.
Q. Do you know Dr. Reyes?
A. I can, I cannot recall when he came to see me.
Q. Okay, and the reason I'm asking, if I brought three people into the room, could you tell me which one was Dr. Reyes?
A. No.
Q. Okay. Did you go back, or did somebody supply you with a roster of attendees and you learned that he attended one of your courses?
A. No, I did not see a roster, but if he testified that, I believe he testified that he came to see me.
Q. You're relying on what Dr. Reyes said, not your memory?
A. Not my memory, no.
Q. Okay, you don't remember the guy, nobody has told you in the record that he's ever been in any

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of your classes, you're simply relying on what his testimony was?
A. That's correct.
Q. Do you recall what the class was that you taught?
A. No, I don't recall the specific one.
Q. You said I've trained pelvic surgeons including Dr. Reyes. You don't know that, you're just --
A. I know by what has been said, okay, he came to see you.
Q. Okay. All right. You say, quote, "The IFU was taught during these training sessions as well as a surgeon-to-surgeon discussion of technique, placement, risks and treating complications." Do you see that?
A. Yes.
Q. You don't know what you taught him, so you don't know what was taught?
A. If he came to see me in a cadaver lab, I had a system for every time I would go, we would go into the specimen, and that system consisted of opening the IFU, and every time that I had the three or four doctors dissecting the cadaver with me, the program was always the same, we're going to insert it, we're going

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to look first through the IFU, and from beginning to completion, I want you all to be familiar with this, because at the end of this, you're going to have this document going with you, going with you home, when you're home.
Q. And am I correct that you are instructed by Ethicon to, to teach from the IFU, that is supposed to be your guide?
A. I do not remember having those specific instructions that you have to teach by the IFU, but if I'm opening the device, I'm going to use the IFU.
Q. Because it's there, right?
A. The IFU is right there.
Q. And you understood that you were not supposed to teach anything that was inconsistent with the IFU, correct?
A. I have no reason to teach anything that was different.
Q. I understand, but you understood that Ethicon told you, because of regulatory reasons, you can't, you can't represent or teach anything that is inconsistent with our, with our copy-approved IFU?
A. I could not represent anything different from what the IFU said.
Q. And you didn't, did you?

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A. I did not.
Q. So up until --when is the last time you did any TVT training, sir?
A. Long time ago, I would say over six years, at least over six years.
Q. Okay, so, 2010?
A. Yes.
Q. Okay. And, so, as of the last time you taught the, any TVT training, you would have been using the, the applicable IFU, correct?
A. Yes, for any, any device, I always started with the IFU.
Q. And you realize that the, that the warnings in the TVTO IFU haven't changed in any material way since 2004 to 2015?
MS. GALLAGHER: Object to form.
A. I, I, I've heard, I overheard, this is just hearsay, that they have changed. I haven't looked at an IFU, even though I place, specifically this last Monday, you know, Monday or, yeah, this week, I have not, did not look at the IFU.
BY MR. REESE:
Q. When is the last time you looked at the IFU to TVTO?
A. Probably the last course that we went

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through.
Q. About six years ago?
A. About six years ago.
Q. And whatever was in that TVT IFU in 2010 is what you taught physicians about the risks, complications, adverse effects of the use of the product, correct?
A. That was what we used for, to explain to the physicians.
Q. Okay. You said, Doctor, that there was a much higher risk of major injury from the hysterectomy to which Jennifer consented, especially as to complaints of pelvic pain and dyspareunia. Do you see that?
A. Yes.
Q. What complications do you believe were caused by her hysterectomy, if any?
A. There is a higher risk of dyspareunia from a hysterectomy than from a sling.
Q. Well, I hear that, but that's not my question. What if any complications do you believe Jennifer is suffering from today that was caused by the hysterectomy?
A. The pain on deep penetration on the left side.

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Q. Okay. And why is that?
A. Because, although this was a laparoscopic hysterectomy, the closure was the same closure that is used in a vaginal hysterectomy, and patients that have a vaginal hysterectomy have a risk of having dyspareunia and pelvic pain, especially if, as it was in her case, not properly healed.
Q. And so you believe her dyspareunia is caused by a complication from a hysterectomy?
A. Yes.
Q. Do you believe that her groin pain is caused by a complication of the hysterectomy?
A. The groin pain is likely caused by the hysterectomy, and the procedure itself, the sling, the sling can produce groin pain, but there's a closer proximity from the vaginal cuff to the groin than from the sling.
Q. Okay. Vaginal pain, groin pain. Any other complaint that Jennifer has that you think was caused by the hysterectomy, or complications from hysterectomy?
A. Yes, basically the pain and the, and the dyspareunia, and I also believe that the hysterectomy, the uterus being central to the support on the upper third of the vagina also produced the vagina to come

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down and contribute to the bowstring sensation that Dr. Graham felt.
Q. Okay. We'll talk about that also in a second. So, the dyspareunia, pelvic pain and bowstringing of the mesh were caused by the hysterectomy?
A. The hysterectomy contributed to it.
Q. Okay. Did any other doctor conclude that a complication of the hysterectomy caused any of those problems, other than you?
A. Repeat that.
Q. Yes, sir. I understand Dr. Sepulveda says the hysterectomy caused the dyspareunia, it caused the groin pain, it contributed to the bowstringing of the mesh. Correct?
A. Yes.
Q. Did any other doctor who actually treated her reach that conclusion?
A. No.
Q. Okay. And Dr. Reyes laid hands on her, correct?
A. Yes.
Q. He didn't reach that same conclusion, did he?
A. No.

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Q. Dr. Graham laid hands on her, did he not?
A. That's correct.
Q. He did not reach that conclusion, did he?
A. He did not.
Q. Dr. Zimmern laid hands on her, didn't reach that conclusion, did he?
A. No.
Q. Dr. Chen saw Jennifer, did she not?
A. Yes.
Q. She did not reach that conclusion, did she?
A. No.
Q. You are the only doctor that says the hysterectomy is causing any of her complications?
A. I'm the only physician to my knowledge that has mentioned that.
Q. Doctor, I want to make sure that you and I are saying the same thing. I'm saying do you have an opinion whether or not the hysterectomy caused any or all of these problems, and you're answering it contributed to it. So, I want to make sure we're on the same page. When you say contribute, do you mean cause?
A. Well, she had two surgeries. She had the hysterectomy, and then she has the, the, she had the

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sling and she had the hysterectomy. In addition to that, then she had the revision surgery.
Q. Surgeries?
A. She has more than, yes, so there are two, she had the, the sling, the hysterectomy, the revision by Dr. Graham and the revision by Dr. Zimmern.
Q. Yes, sir. When I asked you did the hysterectomy, or complication from the hysterectomy cause the dyspareunia, cause the pelvic pain, cause the bowstringing, and you said it contributed to it, you're saying it contributed to causing all those things?
A. It contributed to, I see that as an explanation for the symptoms that she has. I know that dyspareunia, that there was a pain during sex that was referred on the left side before she saw Dr. Graham. Once she had that, that revision, dyspareunia cleared and she did not refer to dyspareunia for over a year. So, the hysterectomy contributed to the lack of support in the area, that was obviously a relaxation in the compartment of the pelvis, and what was placed when the upper part came down, that's what you felt.
Q. Did the mesh contribute in any way to any of the injuries or, or harm that Jennifer is claiming in this lawsuit?
A. There's more evidence pointing out to all

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the other etiologies or causes that we already saw, than to the mesh by itself causing pain.
Q. That's not my question. I'm asking you, did the mesh in any manner, in any percentage, contribute to causing any of Jennifer's injuries?
A. No, I don't believe that's --
Q. So you're saying not only was it, you're saying there's other things that were more likely, you're saying definitively, it played zero percent in causing her dyspareunia, zero percent in causing any groin or vaginal pain, zero percent in causing any bowstringing, any of the bowstringing of the mesh itself?
A. I think when you rule in and you rule out things, you cannot go by a zero percent or one percent. You can say that on the context of a randomized control trial, but when you look at the different causes, rule it in and rule it out, I can rule out mesh as the immediate cause of her pain based on the evidence that mesh by itself does not cause pain.
Q. Well, what is -- mesh does not cause pain?
A. No.
Q. Okay. Why is it in, why is it in the IFU then? That's a complication of the use of mesh.

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A. I think that's, what's included in the IFU is not pain just because of the mesh. It's pain of any surgery that would include an implant, so --
Q. Including mesh, though?
A. Including mesh. That's explained in the IFU. Why did they decide to put pain in that specific area? I don't know. I can tell -- what I do know is that mesh by itself, just leaving polypropylene in that area will not cause pain.
Q. Even though the IFU says that it can?
A. Even if the IFU says that, I can tell to my patient, I can look at my patients in the eye and tell them mesh by itself do not cause pain.
Q. I understand. Even though the IFU for the mesh written by Ethicon says it can cause pain?
A. That's correct, even when they say it can cause pain.
Q. And it says it can cause dyspareunia, correct?
A. It says it can cause dyspareunia, yes.
Q. And it says it can cause nerve damage?
A. Yes.
Q. Okay. You just disagree that it can do any of those things, even though Ethicon admits that it can?

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A. It's there in the IFU, and it has been described without validation. I can, from a biological point of view, there's no evidence that leaving a piece of mesh on tissue causes pain by itself.
Q. So, in your view, Doctor, is mesh capable of causing any injury to a woman, of any kind?
A. I think that when you place it in the, in the safe area that it's used for, for slings, it should not cause an injury.
Q. So it's your testimony that a sling, if properly placed, is impossible of causing any injury to anyone?
MS. GALLAGHER: Objection, form.
A. By itself, a sling, any surgery for incontinence obviously can produce pain. Any surgery for incontinence can produce dyspareunia. It's just that to do the surgery with mesh doesn't contribute over what we know already about continence procedures.
BY MR. FREESE:
Q. So, in your opinion, the hundred thousand lawsuits that are pending in this country against Ethicon and AMS and Bard and Boston Scientific, every one of them are frivolous, correct?
MS. GALLAGHER: Object to form.
A. No, I did not say that.

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BY MR. FREESE:
Q. Let's talk about it. You believe every one of those cases are frivolous because mesh can't possibly cause any of these injuries?
MS. GALLAGHER: Object to form.
A. I don't think that I will have enough hours in my day to look at each one of them. I can only give an opinion of the ones that I have reviewed.
BY MR. FREESE:
Q. And of the ones you've reviewed, a hundred percent of the time you've said the mesh didn't cause any harm to the woman, correct?
A. The pain caused directly by the mesh, I can say that mesh by itself does not cause pain.
Q. One hundred percent of the time on cases you've reviewed for Ethicon, you've said the mesh caused no harm to the woman, correct?
A. That's correct.
Q. You will agree that the FDA believes that the mesh is capable of causing pain in and of itself, do you not?
A. By itself, an implant of mesh or polypropylene?
Q. Yes.
A. They, they say that there were reports of

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it, we have gone over the MAUDE database, and there are reports, even in trials, of mesh causing pain, the procedure using mesh causing pain. It's just that when we look at the different procedures, for example, we look at the trial for colposuspension, the rate of pain is higher.
Q. That's not my question, Dr. Sepulveda. You understand that the FDA says that synthetic midurethral slings can cause dyspareunia, can cause pain?
A. Yes, that's in the warning.
Q. And the FDA is saying, in addition to the warning, the FDA says it, correct?
A. Yes, they said it, that's the only way that they have communicated about this, to my knowledge, through the warning.
Q. And you just don't believe it?
A. I believe that mesh by itself does not cause pain.
Q. You don't believe the FDA when they say mesh complications are caused by the mesh?
MS. GALLAGHER: Object to form.
A. No, I, I cannot believe or misbelieve it because I'm not aware of them saying exactly mesh is what causes the pain.

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BY MR. FREESE:
Q. Well, you've relied on the Dear Health Care Professional letter that was sent out by the FDA, were you not? The public health notification?
A. Yes, I do remember that.
Q. In fact, you were saying Dr. Reyes was aware of it, too, correct?
A. Yes, with any surgery, mesh or no mesh, there's a risk of pain and there's a risk of dyspareunia.
Q. But you don't believe that there really is, even though the FDA says that?
A. No, what I just say is that mesh by itself is just the whole surgery. What I say is that mesh by itself, just implanting a piece of mesh, just leaving a piece of polypropylene suture on my tissue does not cause pain.
Q. Well, there's more than just laying it. You have to surgically implant it, correct?
A. Well, there is a pubovaginal sling procedure done.
Q. So, the process of implanting mesh is capable of causing pain and causing injury, is it not?
A. Yes, the actual use, or the actual procedure can cause pain.

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Q. And it's your opinion that in this case, neither the procedure nor the mesh contributed in any way to Jennifer's injuries?
A. Yeah, I think that there are things that can be ruled in to the better extent than the mesh.
Q. I understand that and we'll talk about that, but I'm asking you about the mesh. You have ruled it out as a contributor in any way to her injuries, correct?
A. Yes, mesh sitting in there by itself, polypropylene sutures just sitting there by itself do not cause pain.
Q. We're not talking about polypropylene sutures. We're talking about a Prolene mesh, not sutures. You're saying the TVTO sling did not cause or contribute to Jennifer's injuries in any way?
A. Yeah, I don't think, it is my opinion that the TVTO was not the cause of dyspareunia and pain.
Q. Or any nerve damage?
A. No, no nerve damage.
Q. Now, you say the mesh contributed in no way to her dyspareunia, pain, nerve damage. Multiple treating doctors disagree with you, the ones who are not paid to testify do believe that her complications

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were caused by the mesh, correct?
MS. GALLAGHER: Object to form.
A. There are doctors that just look at the mesh as a cause of pain. Case in point, Dr. Graham felt before his surgery, based on his testimony and on the operative report, that the mesh was causing bleeding, that the mesh, the implant, the midurethral sling was causing bleeding and was causing pain, but he discovered during the surgery that the actual source of bleeding was the scars on the vaginal vault.
BY MR. FREESE:
Q. So Dr. Graham thought it was the mesh going into surgery, but after surgery, he concluded that it was the hysterectomy granulation that was causing the problem?
A. Yes, he actually, he actually took the vaginal vault tissue and he took the, the piece of mesh that he felt was a bowstring with the belief that she was going to g
et better, and obviously she continued with it. She continued with the symptoms.
Q. Dr. Sepulveda, I'm going to mark this as Exhibit 16 to your deposition.
(Plaintiff's Exhibit No. 16 was marked for identification.)

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BY MR. FREESE:
Q. These are Dr. Graham's records. Okay? And let's see if his records agree with what you say. I'll just hand you my copy and we'll work on it together. I think it's easier. You see that this is the operative report of Dr. Graham?
A. Yes.
Q. And it's dated December 22nd, 2010?
A. Yes.
Q. All right. And you say Dr. Graham thought it was the mesh that was causing her pain before surgery, but he got in, did the partial revision and came out thinking the hysterectomy was causing the pain?
A. Yes.
Q. Okay. Let's see what his operative report says. Preoperative diagnosis: Pelvic pain from transobturator tape, vaginal bleeding. Do you see that?
A. Yes.
Q. That's before he goes in and does the surgery, correct?
A. Yes.
Q. Tell the jury what his postoperative diagnosis is.

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A. Pelvic pain from transobturator tape and vaginal bleeding.
Q. Well, how can that be? I thought you said he got in there and discovered that it was the hysterectomy causing the pain and not the mesh?
A. Well, before his -- when you look at his records from the preop visit --
Q. All right, let's look at this record. Do you agree with me that his operative report, preop says that the transobturator tape is causing Jennifer's pain?
A. Yes.
Q. He goes in there, he partially removes the left side of the sling, correct?
A. Yes.
Q. Comes out and dictates contemporaneously with his surgery his findings, correct?
A. Yes.
Q. And his postoperative diagnosis is identical to his preoperative diagnosis?
A. He dictated that.
Q. So you would agree with me that your conclusion about what he found is not borne out by Dr. Graham's medical records. He said both before surgery and after surgery it was the tape that was causing

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Jennifer's injury, correct?
A. He used the same diagnosis.
Q. Okay. He found that the pelvic pain was caused by the transobdurator tape.
A. He just used the same diagnosis.
Q. All right. Well, he's saying that the reason that I thought the tape was causing pain after surgery was in fact the very same reason he thought before surgery, correct?
A. Yeah, but I just, I just say he used the same diagnosis, and we use diagnoses like that every time we dictate to say the diagnosis is the same.
Q. I understand, but that's inconsistent with your testimony, isn't it?
A. No, it's not.
Q. You're saying Dr. Graham went in and preoperatively said it was the tape and postoperatively said it was the hysterectomy that was causing her pain.
A. No, he cannot say that the hysterectomy caused it, because the hysterectomy happened remotely to it.
Q. Well, but you're saying it. She had the hysterectomy six years ago, but you have no hesitation six years later saying that the hysterectomy is causing her pain, not the tape, right?

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A. He wouldn't know --
Q. Correct? You're saying six years after the fact that the hysterectomy caused the pain. Correct?
A. Yes.
Q. You weren't there for the hysterectomy, correct?
A. No.
Q. Okay, and you're saying Dr. Graham wouldn't know because he wasn't there for the hysterectomy, correct?
A. No.
Q. But he did the revision surgery, did he not?
A. Yes, he did.
Q. And he concluded it was the tape that was causing the pain, not the hysterectomy, correct?
MS. GALLAGHER: Object to form.
A. No, he revised, he revised the vaginal vault.
BY MR. FREESE:
Q. Sir, I'm not arguing that he revised the vaginal vault. He dictated that postoperatively the pain was caused by the TVTO tape, correct?
A. Yes.

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Q. That is inconsistent with your testimony, is it not?
A. No, that's -- yeah, that is inconsistent with my testimony, that is correct.
Q. And you would agree with me nowhere in his postoperative report does Dr. Graham mention the hysterectomy as causing or contributing in any way to Jennifer's pain?
A. No, it's the substance of the report shows that he revised the vaginal vault. There was no way there was going to be a scar in the vaginal vault if she would not have had a hysterectomy.
MR. FREESE: Move to strike.
BY MR. FREESE:
Q. Dr. Sepulveda, you're not listening to my question. He, in his postoperative diagnosis, nowhere suggests that the hysterectomy played any role in causing Jennifer's pain, correct?
A. He does not say that in his postoperative diagnosis.
Q. And that is inconsistent with your testimony, is it not?
MS. GALLAGHER: Object to form.
A. That is inconsistent with my testimony.
BY MR. FREESE:

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Q. Okay. And he says that on palpation I was able to feel the left side of her transobturator mesh at its insertion into the obturator muscle. Do you see that?
A. Yes.
Q. Is that an expected outcome? Do you expect the doctor to be able to palpate the mesh after it's been implanted for six months or a year?
MS. GALLAGHER: Object to the form.
A. Under normal circumstances, you don't feel the tape. There are instances in which you can feel the tape if you palpate hard enough.
BY MR. FREESE:
Q. But if this was what you would expect, Dr. Graham wouldn't have been able to feel that tape; that's an unwanted result if you can palpate the tape, correct?
A. No, you can actually feel the tape and you can feel the tape when there's hyper-relaxation of the side wall.
Q. Okay, well, he doesn't say that. He says he was able to palpate. He's not talking about relaxation. Let me just ask you this way, then. Is Dr. Graham reporting that the fact that him palpating the tape is a normal finding or abnormal finding?

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A. No, that's a finding that you can, you can feel or you can describe in, in other slings. On this specific case, the reason why, why he takes Mrs. Ramirez to the operating room is because he feels that this is what's causing the pain.
Q. I understand that, he's felt before the surgery and after the surgery it was causing her pain, correct?
A. Yeah, he has the impression that's what's causing the pain, that that area that he palpated, that area of the bowstringing is what is causing the pain. He documents that, and after he does his surgery, he is certain that, because he put it on his postdiagnosis, that that's what caused the pain.
Q. Okay. And you just think he's just flat out wrong?
A. I think that I would not character it as flat out wrong.
Q. I'm sorry, you think he's wrong?
MS. GALLAGHER: Form.
A. I think that the assessment of this sling causing the pain in the presence of scar tissue is general and is not accurate.
BY MR. FREESE:
Q. Okay, he's wrong. I mean, that's,

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inaccurate is a nice way of saying he's wrong.
A. No, inaccurate is inaccurate, wrong is wrong. Wrong would have been if he goes in there and says this is the cause of any other, any other symptom. No, he feels that that's what's causing the pain, and he had the advantage of examining Jennifer ahead of time.
Q. He did, and he had the advantage of examining her ahead of time and after he did the surgery, and his conclusion after he had that advantage of before and after was that the tape was causing her pain, correct?
MS. GALLAGHER: Object to form.
A. That's his assessment.
BY MR. FREESE:
Q. Now, real quick on this bowstringing. Are you saying that is a finding, a normal finding of how the tape should feel, in a bowstring?
A. No, every time you place a sling you can feel that, but there are other things that contribute to you feeling it.
Q. And we're going to talk about that. I'm simply asking you, is the finding of the mesh being palpable and bowstringing, is that a normal finding in your view?

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A. No, palpating the sling and feeling pain when you palpate the sling is not a normal finding.
Q. And that's what Dr. Graham found, isn't it?
A. He did not word it like that, but he obviously, from his diagnosis, that's what he felt.
Q. And you just think he's not right?
MS. GALLAGHER: Object to form.
A. I just, I just gave testimony on what he --
BY MR. FREESE:
Q. I'll withdraw the question. He did, he was able to induce pain on the left side along the mesh, was he not?
A. I don't see a reason why anyone would take someone to the operating room if there's no pain on that side.
Q. Was Dr. Graham's surgery medically necessary?
A. I think that at the time that he did it, was what he felt was an appropriate way to, to handle it.
Q. Can you answer my question now? Was Dr. Graham's revision surgery and taking 1.5 centimeters of mesh out of Jennifer a medically necessary procedure?

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A. It's as necessary as the excision of the vaginal vault.
Q. And you have no criticism of Dr. Graham for doing that surgery?
A. I do not have any criticism of Dr. Graham for performing that surgery.
Q. And taking 1.5 centimeters of that TVTO sling was both in his judgment correct and in your judgment the correct and necessary thing to do medically?
A. I don't think that he could have offered much more beyond, if he felt, if he felt that, you cannot offer much more.
Q. And am I correct, Dr. Sepulveda, we will find nowhere in Dr. Graham's medical records where he imputes or finds that the hysterectomy in any way caused or contributed to Jennifer's injuries, can we agree to that?
A. There's no, no description of it, but afterwards, he documents that he had to, he had to take a piece of scar tissue from the vaginal vault.
Q. I understand, but he nowhere says that was the cause of her pain, does he?
A. No, he does not place that as a cause of her pain.

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Q. Only you did that.
MS. GALLAGHER: Object to form.
A. Yes.
BY MR. FREESE:
Q. Doctor, you performed a differential diagnosis on Jennifer?
A. As much as I can, I performed a, through the, through all this, all these documents, I, I did perform a differential diagnosis when she, I actually performed a diagnosis when I examined her. But, yes, I, as I see the whole, the whole extent of the whole content of the medical records, I, I'm considering things that I can rule in or I can rule out.
Q. Yes, sir. So, my question is, when you were forming your opinions, were you attempting to rule out or rule in mesh as a cause of Jennifer's pain when forming your causation opinion?
A. I considered all the factors. I considered the surgery, the mesh, the hysterectomy, and I looked at what are the, what are the risks that has been described with these surgeries for each one of those conditions.
Q. So you're saying you both attempted to rule it out and rule it in?
A. Yes, I actually look at what's more

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frequent, what's statistically more frequent, what is more likely, what is less likely.
Q. Can you tell me every reason that you rely on to give the opinion that you ruled the mesh out as a cause of her pain?
A. When you're, when you're doing your differential diagnosis, there is a hierarchy of things that are more frequent and less frequent. When you're ruling in and ruling out different conditions, you have a hierarchy of, of things that you can, you rule in and you rule out, and part of it is how frequent each complication is, and part of it is what were the different components to, to the surgery.
Q. Okay. And, so, just so I understand, I'm trying to move us along here, so I understand it, are you saying you ruled out the mesh because statistically speaking, complications like Jennifer is complaining about statistically happen more in hysterectomy surgeries than mesh surgeries?
A. There's a higher risk of dyspareunia and pelvic pain associated to hysterectomy, especially to vaginal hysterectomy, than to midurethral synthetic sling.
Q. Okay. Which this was not a vaginal hysterectomy.

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A. Actually, the only thing that was not vaginal was the, the taking of the ligaments on the upper part of the uterus, because on her vaginal closure, Dr. Reyes specified that he closed the vagina from the vaginal approach.
Q. Was the hysterectomy medically necessary?
A. In Dr. Reyes' judgment, which I would defer to him, it was necessary.
Q. Do you have any criticism at all about Dr. Reyes?
A. No, I don't have a criticism of how he actually chose the procedures for Jennifer.
Q. So you have no criticism of him choosing the TVTO, correct?
A. No, I think he did that on his best judgment.
Q. Based on everything you can tell, Dr. Reyes implanted the TVTO in precisely the way that Ethicon's instructions for use instructed him to do it, correct?
A. I have no way to actually say that that's the way he did it, I wasn't, I was not there obviously, but what I can get from the records, he describes a procedure that is in accordance to most procedures that I have read.

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Q. Okay. So, based on what you know, Dr. Sepulveda, Dr. Reyes implanted the TVTO in precisely the way Ethicon told him to?
MS. GALLAGHER: Objection to form.
A. He implanted the, I would agree that he implanted the TVTO in a way that is explained on the instructions for use.
BY MR. FREESE:
Q. Then he did it the way Ethicon told him to?
A. Well, I don't want to say that Ethicon will tell him how to do it. I will have to say that he used what's included on the procedure, and he also used his knowledge of how to do a sling.
Q. We're talking past each other. I'm simply trying to get you to agree with me that, based on your review of all the records and the deposition testimony, Dr. Reyes implanted the TVTO in the manner described as proper in the eye of you?
A. I would agree with that.
Q. Okay, thank you. And you don't ascribe any blame for any of Jennifer's problems to the device or the manner in which Dr. Reyes implanted the device in Jennifer?
A. I agree with that, too.

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Q. Doctor, on page, my page 57, it's the paragraph that starts once placed a mesh. Do you see that?
A. Yes, I do remember that. But I'll find it. Yes.
Q. So, if you'll drop down about halfway, there's a sentence that says, quote, "A torn levator muscle, a thin pubococcygeus muscle or relaxed ATFP will provide very little support to a sling."
A. Yes.
Q. Now, I want to talk about that. Why is that significant to your opinion?
A. It's something that we found on the cadaver dissections. If we would use a cadaver and we would detach the different areas of support, the sling fell down with the, with the areas of support. In other words, the, the sling holds on the same line that the periurethral support holds. If you detach any of the components of the periurethral support, you will tent the sling down.
Q. Okay. And do you have an opinion that Jennifer suffered a torn levator muscle?
A. Levator muscle injuries are frequent.
Q. Okay, that's not my question. I didn't ask you how frequent it is. Do you have an opinion

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whether or not Jennifer had a torn levator muscle?
A. Yes.
Q. Okay, and your opinion is she did have a torn levator muscle?
A. Yes.
Q. That's the same thing as a levator avulsion, correct?
A. Yes.
Q. That's the phrase you used in your report is that she had a levator avulsion.
A. That is correct, that's the phrase I used.
Q. And that's a separation of the musculo-tissue from the pubic bone?
A. That is a separation of the, of the levator, which is composed by different muscles, from the pubic bone.
Q. When did she suffer this levator avulsion?
A. At the time of her deliveries.
Q. Well, at the time of her first delivery?
A. That's when most of the injuries are sustained.
Q. You didn't see any records after her first delivery reporting a levator avulsion, correct?

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A. No.
Q. Okay, she had a second delivery. Do you think that's when this avulsion occurred?
A. I would say that it most likely happened in the first one. Second and third one contributed to it.
Q. Can we agree, Dr. Sepulveda, that of her three vaginal deliveries, not a single treating physician ever diagnosed her with a levator avulsion?
A. I agree with you on that.
Q. Okay. And can we agree that Dr. Reyes, who did pelvic surgery on her, did not find a levator avulsion?
A. I agree with that.
Q. Dr. Graham did not find a levator avulsion, correct?
A. No.
Q. Dr. Zimmern did not find a levator avulsion, correct?
A. He may have encountered a levator avulsion or defined an upper levator avulsion.
Q. He doesn't say that anywhere, does he?
A. No, he does not.
Q. Dr. Chen does not find that, does she?
A. No.

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Q. Dr. Carey did not find a levator avulsion, did she?
A. No.
Q. Dr. Scott did not find a levator avulsion, did she?
A. No, she found the features of a levator avulsion.
Q. Doctor, did she diagnose levator avulsion?
A. No.
Q. Did Dr. Margolis find a levator avulsion?
A. No.
Q. There are at least seven to ten doctors who have worked or performed medical procedures on Jennifer, from her, from her childbirths through her pelvic surgeries. Right?
A. Yes.
Q. None of them found that she had a levator avulsion except you, correct?
A. None of them diagnosed it.
Q. You were the only one to find this avulsion, correct?
A. That's correct.
Q. And you think that this avulsion that no other doctor could find and no other doctor diagnosed

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was the cause of the bowstringing of her tape?
A. I believe it has been there all along.
Q. That was my point. You believe this levator avulsion existed before she ever saw Dr. Reyes for the implant to start with?
A. Yes.
Q. And what is the basis of that opinion?
A. It's the, the papers on levator avulsion.
Q. That was a poor question. Let me ask a better question. What in Jennifer's medical records lead you to believe that she had this levator avulsion?
A. Well, she had a, first she had three vaginal deliveries. Second, there was hypermobility of the urethra.
Q. When was hypermobility of her urethra first reported?
A. On Dr. Reyes' examination.
Q. Okay.
A. Then, the hysterectomy was a precipitating factor on making the avulsion evident.
Q. The hysterectomy took an existing levator avulsion and aggravated it?
A. Yes.
Q. All right.
A. The levator avulsion manifested then on

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the feeling of the bowstringing on the side. It continued to cause pain during activity.
Q. What pain and during what activity?
A. The pain that she testified that she was having when she would just go on an activity, when she would stretch.
Q. Okay, the pain that she reported post-implant, correct?
A. That's correct.
Q. She didn't report any of these, that pain pre-implant, correct, this activity pain?
A. No, there was a report of dyspareunia and pelvic pain before, but you cannot relate that to a levator avulsion.
Q. This fact of pain during activity that Jennifer reported, exercise and stretching and all that --
A. Yes.
Q. -- that was after the mesh, correct?
A. After she had the surgeries.
Q. Okay. Never reported that prior to the mesh implant?
A. No.
Q. Okay. Go on, I didn't mean to stop you.
A. And then the, the pain, the pain after

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the, after the implant where the ischiorectal fossa was approached -- I'm sorry, I'm going to rephrase that. The pain after the explanting surgery, where the ischiorectal fossa was approached.
Q. Okay. Which explant surgery, Zimmern's or Graham's?
A. The one that she had with Dr. Zimmern.
Q. Okay. I'm sorry, I'm not understanding which pain you're talking about. The pain -- can you say it again?
A. The pain after the explant surgery performed by Dr. Zimmern where the ischioanal fossa fat was exposed.
Q. Go ahead.
A. The contraction of the right levator, described by Dr. Kelly Scott, with the low tone described by 1 out of 5 on the left side, and my exam in which I placed a Q-tip on the vagina and saw the orientation of the vagina dropping from the left side and keeping the right side up.
Q. That was during your IME?
A. Yes.
Q. Okay. So, Dr. Scott made some findings that you think demonstrate this levator injury, right?
A. Yes.

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Q. But she didn't diagnose that, did she?
A. No.
Q. Let me ask you this, Dr. Sepulveda. You're not licensed to practice medicine in Texas, are you?
A. No.
Q. Never have been?
A. No, never have been.
Q. You know all of Jennifer's treating doctors are all doctors licensed to practice medicine in the state of Texas?
A. Yes.
Q. Okay. How did all these Texas licensed doctors miss, over all these years, what you were able to find in a few-minute IME?
MS. GALLAGHER: Object to form.
A. I did not find it in a few-minutes IME. I actually looked at the whole continuum of care. Why, why was I able to find it, what is the difference in terms of certifications or qualifications between me and all the other doctors that are in this case? There's one exam, and it is the Pelvic Rehabilitation Practitioner certification.
Q. Is this that Wallace thing?
A. Yes, this is the Herman & Wallace

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certification, yes.
Q. Okay, so that Wallace certification is what makes you more qualified to make this diagnosis than all these double board-certified physicians?
A. I am --
MS. GALLAGHER: Form.
A. -- double board-certified, too.
BY MR. FREESE:
Q. I understand, but the only thing that makes you different, sir, is that you have this, this certificate from this, this little organization in Seattle that trains physical therapists, right?
A. Right.
MS. GALLAGHER: Object to form.
BY MR. FREESE:
Q. What's the full name, Wallace what?
A. It's Herman & Wallace Institute for Pelvic Floor Rehab.
Q. Okay, and the fact that you hold that certification from them gives you the qualification to make this levator avulsion diagnosis that every, every doctor that treated Jennifer seemed incapable of finding, correct?
MS. GALLAGHER: Object to form.
A. In addition to my double certification in

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pelvic floor rehab, yes.
BY MR. FREESE:
Q. We've got other doctors that have that, don't we? Zimmern's got that, Dr. Margolis has got that.
A. Yes.
Q. Okay. But they don't have the Wallace physical therapy certificate?
A. If that's the way you want to refer to it, it's your deposition.
Q. What did you do? It was like, like a hundred multiple questions or something? What did you do for that certificate, sir?
A. It's a five-hour exam.
Q. Okay, and just, like a multiple choice test?
A. Yes.
Q. Okay.
A. With clinical scenarios.
Q. Anything other than a multiple choice test?
A. No, it's clinical scenarios and it's a secure examination.
Q. Okay. Who has been published in more peer-reviewed journals regarding complications arising

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out of surgery from pelvic mesh, Dr. Zimmern or you?
A. No, he has had more publications on mesh. That's one thing that he concentrates on.
Q. And to be a peer-reviewed author like he is, that means all the experts in the field, that is the doctors who do this for a living, like what you do, they look at his work and say, okay, this is either good science or this is crappy science, right? That's what they do, peer review, right? They look at it and say this is good, reliable science or it's not, correct?
A. Can, can you show me a peer-review article from Dr. Zimmern on mesh?
Q. Sure.
A. One peer-review article? Peer review, I'm not talking about editorials, I'm talking about peer review, randomized control trial on mesh, can you show me one?
Q. A randomized control trial? No, I don't know if I can or not.
A. I would welcome to read that any time you provide me with that.
Q. You have not peer reviewed a single thing that he has published, have you?
A. What's your question?

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Q. You have not peer reviewed a single article of his, have you?
A. No, I have not.
Q. But his articles are peer reviewed, are they not?
A. I just don't know if there's any publication that I'm aware of that I have not seen, that I have, I may have missed on the course of this litigation about a peer-review article from Dr. Philippe Zimmern or any other doctors that you mentioned, on mesh.
Q. Okay. And if those exist, would you modify your opinion?
A. If those would exist, I would welcome reviewing it and modify my opinion accordingly.
Q. Okay. Well, how would you modify your opinion? I mean, would you agree with Dr. Zimmern's conclusions and say, you know what, he's got a peer-reviewed publication, I don't, I would probably defer to him on his conclusions on what is causing Jennifer's problems?
MS. GALLAGHER: Object to form.
A. I think that most of the doctors are taking care of patients.
BY MR. FREESE:

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Q. Answer my question, Dr. Sepulveda. If I showed you a peer-reviewed article from Dr. Zimmern on pelvic mesh complications, will you then defer to his conclusions on what was caused Jennifer's problems?
MS. GALLAGHER: Object to form.
A. If I find a peer-review article that supercedes any of the available evidence that we have now of randomized control trials or cohort studies in a good sample, I will be willing to modify my opinion.
BY MR. FREESE:
Q. And we know you've never been peer reviewed in any kind of publication regarding pelvic mesh, correct?
A. No. I just take exams.
MS. GALLAGHER: Are you moving to something else?
MR. FREESE: I can. You want to take a break?
MS. GALLAGHER: No, because he hasn't finished the levator stuff. He's talked about what he saw in the records, but he hasn't talked to you about images yet, so I don't think you're done.
MR. FREESE: You want to just give me his testimony there?

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MS. GALLAGHER: Well, I want you to get all of his opinions. You started making fun of his certifications before you got all of his reasons for the levator.

THE WITNESS: Can we take a five-minute break?

MR. FREESE: Of course.

(A break was taken from 2:27 p.m. to 2:33 p.m.)

BY MR. FREESE:

Q. We're going to get back to levators, but real quick before I forget, the Wallace Institute, am I correct, sir, that you don't even list it on your CV as one of your qualifications?

A. It may have been missed from it. I may have had it --

Q. Well, here's your CV that you attached to your report here.

(Plaintiff's Exhibit 17 was marked for identification.)

BY MR. FREESE:

Q. How long have you held this certification from the Wallace Institute?

A. I think it's about two years.

Q. Two years, okay, and you realize this is

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the CV that you produced this week to us, Exhibit 17?

A. Yes.

Q. And that Wallace Institute certification doesn't appear on your CV, does it?

A. No, I actually missed to place it in.

Q. Okay. Is it anywhere on any CV that you prepared?

A. No, I'll update it, I'll update it, I'll send you an updated copy.

Q. So, do I not have the most updated version of your CV?

A. I thought it was, until now that you pointed out that I haven't included that certification.

Q. Am I correct that 90 percent or more of the members of that institute aren't even medical doctors?

A. No, they're therapists, they're doctors in physical therapy and rehabilitation.

MR. FREESE: Move to strike.

BY MR. FREESE:

Q. Dr. Sepulveda, am I correct that more than 90 percent of the people who hold that Wallace certification are not medical doctors?

A. That is correct.

Q. All right. Before our break you were

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telling me the evidence of why you think that Jennifer suffered a levator avulsion and you told me. Then Ms. Gallagher suggested you talk to me about images, so let me ask you about images. What do the images show in relation to your opinion about a levator avulsion?

A. There are two images. One is the ultrasound of the pelvic floor, and the other one is the MRI.

Q. Okay, and I'm going to hand you Exhibit 6 from Dr. Zimmern's deposition. I'm going to hand you a bunch of exhibits from Dr. Zimmern's deposition. Are the images that you're referring to in here, and can you pull them out and show me what you're talking about?

A. Yes. There's the MRI, and there is the ultrasound.

Q. Okay. Pull out everything, every image that you think supports the levator avulsion and we'll mark it.

MS. GALLAGHER: That you're putting in front of him?

MR. FREESE: Yeah, I'm not trying to trick him, this is what I've got. If you have something else, Doctor, please volunteer.

MS. GALLAGHER: I think we've got all of

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the actual films.

MR. FREESE: Okay.

MS. GALLAGHER: Because they're on the CDs. They're not in hard copy.

BY MR. FREESE:

Q. Well, does what I put in front of you adequately allow to you express the opinion about evidence of a levator avulsion, or do you need something else?

A. No, this is, this is, I think, I see two images here that would help me with it.

Q. Okay. I don't want to withhold anything from you that's going to help --

A. But there are two more images on the MRI. These MRI images are exactly the same, the same image.

Q. We don't need the duplicates, then.

A. These are the only one. And there are multiple images on the ultrasound actually.

Q. Okay.

A. Sorry, I correct, there are multiple images on the MRI.

MR. FREESE: Let's mark this as Exhibit 18, and this as Exhibit 19.

(Plaintiff's Exhibits No. 18 and No. 19 were marked for identification.)

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BY MR. FREESE:
Q. First of all, tell us what Exhibit 18 is.
A. Exhibit 18 is a picture of a, four images that are used for a pelvic floor ultrasound.
Q. Okay. And you believe that that, these images help demonstrate the levator avulsion that you concluded that Jennifer has?
A. Yes.
Q. Okay. Can you, I'm going to give you different choices here of colors, you have a pen, can you point to me where in the image is evidence of the levator avulsion?
A. You'll see in here.
Q. Exhibit 18, right?
A. We're on Exhibit 18, and the image that I'm going to, I'm going to write as A, I'm going to go to the one that is B, the other one is C, and the other one D.
Q. Okay.
A. So, I'm going to, these are mid sizeable images.
Q. If you would, let's do it out here in the white so when we copy it we'll know. Would you put A, B, C and D on the white so we can -- or is the placement itself important?

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A. No, no, this is just to, to say that this, this is the image I'm going to refer to.
Q. So put it here in the white so we can see it clear.
A. Okay.
Q. Now, where on Exhibit 18 does it show this levator avulsion?
A. There's, this is midsize images, A and B on this side, both images, and C is a coronal image, and this constructs a 3D rendering of the pelvic floor. Here you see the pubis, here you see the urethra, here you see the tape, clearly there's the tape.
Q. You're on D, and let's go ahead, if you will, let's just pick a color that picks up on this.
A. A line here, and I put tape.
Q. Sure, that's good. Put tape.
A. This is a tape, and this is the vagina, and the vagina is in the form of a butterfly. The vagina is in a form of a butterfly, but on this side, it's just collapsed. It's collapsed on the left side. The vagina just fell down, which is what I had described before.
Q. Okay. So would you pick one of those markers and circle where you say the vagina has fallen down. Use the colors that Jordan brought, it will pick

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up better.
A. This is, I'm going to delineate the normal shape of the vagina, which is in the form of a butterfly, here, and this place is collapsed.
Q. So just put an arrow there, put collapsed vagina. Okay. Now, can I see the avulsion, or is that just evidence of the avulsion?
A. That's what supports, the levator is what supports the vaginal wall, and in this specific case, now we're looking at it, this is an image that should be looked at this way, because the vagina has this shape, and you see no tape here on the left side, and there's tape going to the right side. Same thing here. These are not separate images, this image is a construction of these three images. So you have this, this butterfly with a collapsed vagina here, tape here, no tape on the left side. The urethra is not collapsed. There is no indication of the tape on the urethra, and there's normal tissue between the urethra and the tape.
Q. Can we see the avulsion on any of these images?
A. Not on the ultrasound.
Q. Okay. So, how does a medical doctor diagnose an avulsion?

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A. You suspect it clinically by the deviation of the symmetry of the vagina, and with pelvic floor ultrasound you look at it.
Q. You use an ultrasound to diagnose the levator, do you not?
A. Yes, it's a clinical, a clinical based on subjective data based on what you find in your exam and you confirm it with a pelvic floor ultrasound.
Q. Okay. And this is a pelvic floor ultrasound, correct?
A. This is the pelvic floor ultrasound.
Q. Where is the levator avulsion in here?
A. You see the manifestation of the levator avulsion on the collapsed vagina on this side.
Q. Let me make sure I understand. What you're saying is the manifestation is simply the result of the levator avulsion, correct?
A. Right. If you see, if you're looking at the --
Q. Did I say that correct?
A. You did say that correct.
Q. That's all I'm asking. Are you saying that an ultrasound cannot actually see the levator avulsion itself?
A. Yes, it can, but in this view of the

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ultrasound, you cannot see the levators.
Q. So, in Exhibit 18, we're looking at a pelvic ultrasound, it does not show us a levator avulsion, correct?
A. It does not show the levator muscle. I cannot conclude, based on this image, that there's a levator, except for the vagina being collapsed on this side.
Q. In other words, it's circumstantial, that is the result of a levator avulsion, the collapsed vagina, not the avulsion itself, that's what we're looking at?
A. Yeah, right, the vagina is supported at the level of the arcus tendineus fascia pelvis and the periurethral area, as I explained on my report, it's supported by this arrangement of the levator muscle, the arcus tendineus fascia pelvis and the pubourethral ligament.
Q. And the collapsing of the left side of the vaginal canal, or the vaginal wall --
A. The vaginal wall.
Q. -- is, is your evidence of a levator avulsion in this image?
A. In this image, yes.
Q. Okay. Anything else in Exhibit 18 that

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would indicate a levator avulsion other than what you described for us, Doctor?
A. Just in this image, which is a pure image, it is done at 3D, this is a pure image obtained on the ultrasound.
Q. And Dr. Zimmern ordered this and looked at this, did he not?
A. I don't know if he looked at it.
Q. Well, he said he looked at it, didn't he?
A. I, I think that he testified that he looks at MRIs on Friday mornings, but I don't recall him saying that he looked at the ultrasound.
Q. And if he did look at this ultrasound and didn't see what you saw, Dr. Zimmern just missed this levator avulsion that you've shown us, correct, or the result of the levator avulsion, that is the collapsed left side of the vaginal wall?
A. Yes.
Q. Okay. Let's look at 19. Does this help us, or help you give an opinion that there was a levator avulsion in Jennifer?
A. Yes, there's, there's the levator --
Q. First of all, what are we looking at?
A. We're looking at an MRI image at the level of the urethra showing the levator muscles, the

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urethra, the symphysis pubis, the obturator muscles, the adductor magnus and adductor longus muscle.
Q. Okay. Now, does this image show us the levator avulsion?
A. Yes.
Q. Okay, and can you show us where?
A. Right here.
Q. Okay, and just put an arrow out here and say levator avulsion. All right, and this was ordered by Dr. Zimmern also, correct?
A. Yes.
Q. Okay, and where in that circle you've drawn is the levator avulsion?
A. Well, you can see the muscle going all the way up, and its insertion on the pubis right here, and you see that this insertion doesn't go up. If you put a line, you put the insertion right here, this is the insertion and this is the long insertion.
Q. When you say this is the long insertion, you mean this black triangle here?
A. No, the muscle right here. All this here. And this is, this is all your levator.
Q. Okay. Now, have you ever seen a, an image of an actual levator avulsion?
A. Yes.

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Q. Did you pull one out as a comparator to see if it looked like what you've got here for Jennifer?
A. Yes.
Q. Okay, do you have that with you?
A. Yes. These are images.
Q. First of all, let's mark this and make sure we know what we're looking at. So I'm going to mark as Exhibit 21 ultrasound imaging of the pelvic floor, part 2, three-dimensional or volume imaging in the, published online, Ultrasound Obstetrical Gynecology, 2004.
(Plaintiff's Exhibit No. 21 was marked for identification.)
BY MR. FREESE:
Q. Is that correct?
A. Yes.
Q. And you turned us to page 620, and Dietz I guess is the author?
A. Yes.
Q. And are you actually looking at the book itself?
A. I'm also looking at the book, because I believe I have seen also pictures of a levator avulsion, but we can just go by the, with the paper.

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Q. This is a chapter in a textbook?
A. No, that's a publication. That's a reviewed article.
Q. This is not the published version of this?
A. No.
Q. Okay. Let's deal with this first and then we'll get to that.
A. That is my ultrasound book.
Q. So, Exhibit 21, page 620, is demonstrating what a levator avulsion looks like?
A. Right, this is the magnetic resonance image of a levator avulsion, there you see the levator inserting completely up here, and in here it doesn't insert in a similar way that is happening here.
Q. Okay. So you're comparing Exhibit 19 with image A on page 620 of Exhibit 21?
A. Yes, the only thing is that the levator avulsion on this article is on the right, and here the levator avulsion is on the left.
Q. Okay, but just so I can orient myself, this, is this black spot right here on the right, is that the avulsion?
A. No, there's no avulsion on this side. There's avulsion on this side. You see the muscle

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coming underneath and then it goes up to here, and this is where it avulses from.
Q. So, the avulsion is on the left lower quadrant of Exhibit A?
A. Yeah, but this corresponds to the right side of this image.
Q. So you can you draw a circle around the avulsion in, on page 620-A of Exhibit 21?
A. Yes.
Q. And then just write arrow, avulsion. And what you're saying is that right side avulsion in this Exhibit 21 is the same thing that you're seeing in Jennifer's MRI in Exhibit 19?
A. Yes, it's the loss of continuity of the left levator muscle.
Q. Okay. Now, you said that you have, you have the CD, you have the actual film itself?
A. Yes, I brought those CDs to, as exhibits today because I was required on the order.
Q. Right. I just want to slap an Exhibit sticker on it.
A. I don't know which one exactly it is. I have a group of them here.
Q. All right, let me stamp all of them.
So, what you've handed me, Doctor, are

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six CDs for Jennifer Ramirez, and, with facilities are listed as the University of Texas Southwestern Medical Center, it's got the date it was obtained, correct?
A. Yes, that's the date of service.
Q. Northeast Methodist Hospital, obtained 10/23/14. What is that?
A. I can't remember what it is.
Q. Let's just mark all six of them. This is 20. I know I'm going out of order.
(Plaintiff's Exhibit No. 20 was marked for identification and was retained by Plaintiff's attorneys.)
BY MR. FREESE:
Q. Will these, these are images of the ultrasound and MRI of Jennifer?
A. Yes.
Q. And we can look at Exhibit 20 and see this levator avulsion that you've been discussing in these other exhibits?
A. Yes, the other two, two images that aren't as representative as this one.
Q. There are two other images that are representative of what you've already marked?
A. That aren't as representative as this one.

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Q. Is there anything better to show the avulsion, other what we've already marked?
A. There are two other images that don't have the arrows in the middle.
Q. Do they make it any easier to see the avulsion?
A. No, it essentially confirms this one.
Q. Have you now identified everything that supports your opinion that Jennifer suffered a levator avulsion?
A. This, and the final one that I marked was my physical exam.
Q. Okay, and we're going to get to that. Well, we'll get to it right now.
Now, when did you first diagnose Jennifer with a levator avulsion?
A. When I examined her.
Q. Okay. That was when you saw her in person?
A. Yes.
(Plaintiff's Exhibit No. 22 was marked for identification.)
BY MR. FREESE:
Q. Okay. I'm going to show you Exhibit 22. Is this your record of your exam of Jennifer?

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A. Yes.
Q. Okay. Would you look at your IME, Doctor, and tell me where you diagnosed a levator avulsion in here?
A. I, I confirmed my, my suspicion of a levator avulsion, my clinical suspicion, I should say, my clinical suspicion of a levator avulsion, and I described when I placed, I examined her and I placed a Q-tip in her vagina, right in the middle, and I saw that this, that this Q-tip deviated from one side to the, to the, to the upper side. I asked her to do a valsalva maneuver to push, and I saw how this Q-tip deviated, and this is in, I decided to do it this way because it's a way in which it would not be painful to her, it would just measure the axis, and this is, this correlates with the description by Dr. Kelly Scott of the right side being higher than the left side.
Q. Doctor, am I correct that, that when you do this IME, you were trying to write down all the most important findings that you were making contemporaneously with that examination?
A. No, I'm not writing while I'm examining her.
Q. I know, but when you write your report it's fairly contemporaneous, right, so you remember

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what you just did?
A. Right, and I carry my computer.
Q. Okay. Well, you did the exam on November 12th, 2015, correct?
A. Yes.
Q. And you signed the report on November 23rd, 2015?
A. That's when it's closed.
Q. Okay. What I'm trying to get at is, you did this IME contemporaneously, or at or about the time you did the IME, you prepared the report, correct?
A. Well, no, I examined her, I write down my physical exam, and then I, I go through all the other parts of the clinical history, and I close the encounter later on.
Q. Okay. So, by the 23rd of November, 2015, you had completed this Exhibit Number 22, correct?
A. Right, whenever it says that I closed the encounter, there's a time when it's entered and there's a time when it's closed.
Q. And you were trying to record all the most important findings that you, all the most significant findings that you were discovering in the IME, correct?
A. Yes, I do, I do record it on my physical

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exam.
Q. Would you show me where you diagnosed levator avulsion in your IME?
A. Well, the diagnosis of levator avulsion is a mix of clinical and it's a mix of the x-rays and of the physical findings.
Q. Move to strike. Dr. Sepulveda, would you show me in your IME report where you diagnosed Jennifer with a levator avulsion?
A. Yes, sir. It says Q-tip is deviated downward --
Q. What page are you on, sir?
A. On page 2 out of 4. Q-tip is deviated downward and to the left on the pelvic contraction, upward on relaxation.
Q. Okay. Now, where does the word levator avulsion appear anywhere on there?
A. Oh, this is a physical exam. I don't establish a diagnosis here.
Q. Okay, well, am I correct that the phrase levator avulsion appears nowhere in your IME?
A. You can say that, yes.
Q. And, in fact, it's a critical medical conclusion of the entirety of your opinions, is it not? Because you think it caused a, a number of Jennifer's

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complications here, correct?
MS. GALLAGHER: Object to form.
A. Yes.
BY MR. FREESE:
Q. Yet it appears nowhere in your IME, does it?
A. No, it does not appear in my IME.
Q. And you said you suspected it when you did your IME, correct?
A. Yes.
Q. You don't put anywhere in there that you suspected levator avulsion, do you?
A. No, I just put the physical findings.
Q. Well, you do more than that. Then you have assessments, do you not?
A. Yes, sir.
Q. Okay, let's go to the assessments. Hyperesthesias, what is that?
A. That there is a heightened sensation.
Q. Where?
A. In the, in the vulva.
Q. That's an assessment you made at the time you did the IME?
A. Yes. That has a code.
Q. Postprocedural adhesions of vagina, what

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is that?
A. That is the tenderness that was felt on the upper left of the vagina with my findings of this tenderness being reproduced on palpation and being correlated by Mrs. Ramirez as the pain that she referred during intercourse.
Q. And dyspareunia. You assessed dyspareunia.
A. Yes, dyspareunia is, can be a diagnosis or it can be a description of a symptom.
Q. Which one is it here?
A. It's a description of a symptom because we could not reproduce the actual activity that would lead to dyspareunia.
Q. Well, you have an assessment that she's suffering dyspareunia, do you not?
A. Yes, that's a description, yes.
Q. So, you conclude that she was in fact suffering dyspareunia.
A. That's a diagnosis based on the symptoms.
Q. And that's what you did?
A. I have no, no reason to disregard her symptoms when she's telling me that she had pain.
Q. Okay, what are these codes here?
A. These are the ICD-10 codes.

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Q. Okay. Is there a code for a levator avulsion?
A. There's a, there's a code for avulsion of a muscle, but it's not specifically related to the levator.
Q. Okay, but you didn't put down any avulsion of any muscle as an assessment, did you?
A. No.
Q. How do you treat a levator avulsion?
A. There's a -- it depends on what kind of avulsion you have. It could be partial or it could be total. The treatment of levator avulsion has been described with the use of an implant, with a mesh that actually establishes the, a bridge from the muscle to the upper part of the pubis.
Q. How would Jennifer go about treating this levator avulsion?
A. It's, it's a rehab, you try to compensate with other muscles in that area.
Q. You didn't put that in your treatment here in your IME, did you?
A. No, I'm not allowed to give recommendations on an IME.
Q. Did you tell Jennifer she had suffered a levator avulsion at the IME?

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A. No, I informed Mrs. Ramirez that I would forward this report to the attorneys and that it could be available to her through her attorneys. Through you.
Q. You're saying on the day you performed this IME, you suspected a levator avulsion, yet you didn't report it in your IME?
A. Yeah, I just recorded the physical findings.
Q. Correct?
A. That's correct.
Q. You didn't report any physical findings that said she's got a levator avulsion?
A. No, that's incorrect.
Q. By word, you didn't record anything that said levator avulsion.
A. I did not write the word avulsion.
Q. Dr. Sepulveda, we could look at this document all day long and we won't find the phrase levator avulsion anywhere in it, will we?
A. No, you would not find avulsion in this document.
Q. And this document is the actual physical examination of Jennifer, correct?
A. That's the physical examination of Mrs.

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Ramirez.
Q. And the first time that your diagnosis of levator avulsion appears is in your report that you prepared in this case, correct?
A. Yes.
Q. The one we've been going over all day long?
A. Yes.
Q. Which was signed ten days ago?
A. Yes.
Q. That's the first record I've got of you finding a diagnosis of levator avulsion in Jennifer Ramirez was March 23rd, 2016?
A. Yes, if you say that's the first one, yes.
Q. I'm asking you, did you report levator avulsion to us before, as a diagnosis before March 23rd, 2016?
MS. GALLAGHER: Form.
A. We have not communicated any other way.
BY MR. FREESE:
Q. So, the answer is the first time that you have put yourself on record as saying that Jennifer suffered a levator avulsion was ten days ago?
A. Yes, sir.

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MS. GALLAGHER: Object to form.
BY MR. FREESE:
Q. Four weeks before trial in this case. Three weeks before trial.
MS. GALLAGHER: Object to form.
A. Yes.
BY MR. FREESE:
Q. And I won't find that anywhere in your disclosures, will I?
A. On the --
Q. About opinions you're going to render, what you're going to testify about. The only place I'm going to find levator avulsion in any report you did is the one that's dated March 23rd, 2016?
MS. GALLAGHER: Object to form.
A. Yes, my report. My opinion.
BY MR. FREESE:
Q. Okay. Now, you say in your report that the, that the findings of Dr. Graham were the result of a damaged and relaxed pelvic floor, three previous vaginal deliveries, and the granulation tissue from a hysterectomy.
A. Yes.
Q. Did I read that correctly?
A. Yes, sir.

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Q. I'm a little unclear, Dr. Sepulveda. What findings of Dr. Graham were the result of a damaged and relaxed pelvic floor, three previous vaginal deliveries and the granulation tissue from a hysterectomy?
A. I think this is what we have those pages that are -- let's look through it. I've got it here.
Q. Okay. You say in your report, quote, "The findings described by Dr. Graham were the result of a damaged and relaxed pelvic floor, three previous vaginal deliveries, and the granulation tissue from a hysterectomy," correct?
A. And I also contributed with a lack of fibromuscular tissue.
Q. Let's stop with that sentence. We've already looked at Dr. Graham's operative reports. He doesn't mention anything about a damaged and relaxed pelvic floor, does he, as causing any of her symptoms, does he?
A. No, my opinion is an interpretation of the findings that he had.
Q. Okay, well, let's bypass the interpretation and let's see what he actually said, okay? Do you agree with me that in Dr. Graham's operative report, he does not mention a damaged or

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relaxed pelvic floor as any basis for Jennifer's injuries?
A. No, he does not describe that.
Q. Do you agree with me that he does not mention three previous vaginal deliveries in any manner in his operative report as a basis for Jennifer's injuries?
A. Dr. Graham does not describe that.
Q. And he does not mention granulation tissue from a hysterectomy in any way as causing Jennifer's complications, correct?
A. He does describe that the granulation tissue was causing the bleeding.
Q. Well, here's his operative report. Where does it say the granulation causes bleeding, sir?
A. I then examined vaginally and saw two areas of granulation tissue at the cuff and I excised one portion and closed it with a chromic stitch. There was a smaller area of granulation tissue on the right lateral side of the healing cuff, which I cauterized. That is the cause of the bleeding.
Q. Does Dr. Graham say it's the cause of the bleeding?
A. Well, he's not saying, but it's quite evident that he excised that tissue because it causes

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bleeding.
Q. Okay, does his report say that any bleeding was caused by the granulation of the hysterectomy of the cuff?
A. Well, he has it as vaginal bleeding and he has the granulation tissue that he excises.
Q. Where does he have that, sir?
A. Vaginal bleeding, and then he ties it up here with granulation tissue that he removed.
Q. Yeah, but it says postoperative diagnosis, pelvic pain from transobdurator tape, comma, vaginal bleeding. So, he doesn't say that vaginal bleeding is being caused by the hysterectomy, he says being caused by the transobdurator tape.
MS. GALLAGHER: Object to form.
A. No, I don't think that -- you might want to ask Dr. Graham about that, because I don't see him describing the transobdurator tape as the cause of bleeding. No, that would be an inaccurate characterization of his report.
BY MR. FREESE:
Q. Well, do you agree that the entirety of his postoperative diagnosis is pelvic pain from transobturator tape, comma, vaginal bleeding? Did I read that correctly, sir?

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A. Yes.
Q. Does he say anywhere in the report that the bleeding was because of granulation at the vaginal cuff?
A. No, he just excised the granulation tissue.
Q. Now, I don't want to talk about bleeding. I want to talk about pain for a second, okay? The findings described by Dr. Graham, what findings are you referencing in your report?
A. The, the granulation tissue.
Q. Okay. And you --
A. And the, the bowstringing.
Q. And you just ignore his conclusion that the tape was causing the pain?
MS. GALLAGHER: Object to form.
A. Yeah, I'm not, I'm not following this one.
BY MR. FREESE:
Q. You're saying the findings of Dr. Graham, well, the finding of Dr. Graham is the pain is from the transobturator tape. That's his finding, is it not?
MS. GALLAGHER: Object to form.
A. That's not a finding. That's his conclusion. That's his diagnostic impression.

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BY MR. FREESE:
Q. What's the difference between a conclusion and a diagnostic impression? Let me back up. What is the difference between a postoperative diagnosis and a conclusion?
A. The postoperative diagnosis is your impression of what --
Q. That's not a conclusion?
A. That, that's not a diagnostic conclusion.
Q. So, a postoperative diagnosis is not a diagnostic conclusion?
A. No.
Q. Did I hear you correctly, did you say that?
A. Yeah, I just said that, I just said exactly that.
Q. Okay, your diagnosis --
A. I just said exactly that.
Q. Doctor, we've got to slow down here. It's your testimony that a postoperative diagnosis is a not a diagnostic conclusion?
A. A postoperative diagnosis in this specific scenario is not his postoperative conclusion, because Dr. Graham found granulation tissue on his description of the report, and he does not list that in

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the postop diagnosis.
Q. Do you agree with me that a postoperative diagnosis is a finding?
A. No, a postoperative diagnosis is different from a finding. You make a diagnosis based on your findings. What this postoperative diagnosis does not list is the fact that he found granulation tissue and he excised it.
Q. Yes, it does. It talks about the granulation tissue in the postoperative report.
A. But it's not listed on the postoperative diagnosis.
Q. Here's what I'm trying to figure out, Doctor. You say the findings of Dr. Graham. Do you agree with me that pelvic pain from transobturator tape is a finding of Dr. Graham's?
A. Pelvic pain from transobturator tape is his diagnostic impression.
Q. Doctor, is Dr. Graham's diagnostic -- is Dr. Graham's postoperative diagnosis of pelvic pain from transobturator tape a finding? Yes or no?
A. No, that's his diagnosis.
Q. So, he did not find the transobturator tape was causing the pain?
A. No, that's not a finding. That's not an

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objective finding.
Q. Is it a subjective finding?
A. Yeah, that's his clinical impression.
Q. I'm trying to figure out, Doctor, why you say all these things are the findings described by Dr. Graham when his operative report doesn't say any of them. The one thing he does say is that the pain is caused by the transobturator tape, and you don't even list it as a finding by Dr. Graham.
MS. GALLAGHER: Object to form.
BY MR. FREESE:
Q. You understand my curiosity with that?
A. So, what is the question?
Q. The question is, you're saying the findings described by Dr. Graham were the result of, and you rattle off three things, none of which is in Dr. Graham's operative report, but the one thing that is, that is the pain is being caused by transobturator tape is not even listed in your findings.
MS. GALLAGHER: Object to form.
A. I'm giving a diagnostic impression here.
BY MR. FREESE:
Q. Am I accurately stating it?
A. No, I did not list in my diagnostic impression the finding from Dr. Graham, or the

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diagnosis as you say, the diagnosis that Dr. Graham made.
Q. But you're attempting to report what Dr. Graham's findings were, correct? You're reporting Dr. Graham's findings, are you not?
A. Yes, it's --
Q. Stop. You're reporting Dr. Graham's findings, correct?
MS. GALLAGHER: Let him finish his answer.
MR. FREESE: It's a yes or no question.
MS. GALLAGHER: Okay, you cut off the explanation. Go ahead.
BY MR. FREESE:
Q. You are reporting Dr. Graham's findings in your expert report, are you not, Dr. Sepulveda?
A. I am reporting my impression of the operative report that I reached from Dr. Graham.
Q. And your impression excludes the one thing that he says caused the pain, which was transobturator tape, correct?
A. Yes, because I don't believe that a transobturator tape is causing the pain.
Q. But your report isn't giving your opinion; you're trying to report what Dr. Graham's

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findings are, correct?
A. I cannot report on Dr. Graham's findings. Dr. Graham's findings are documented in his operative report.
Q. Which is inconsistent with what you're saying his findings were.
A. I say that the result of his findings are in this explanation. This is what explains the result of his findings.
Q. Dr. Sepulveda, your quote, the findings described by Dr. Graham, let's stop with that right there, the findings described by Dr. Graham. You agree with me those findings are contained in Exhibit 16, are they not?
A. Repeat that question.
Q. Yes. The findings of Dr. Graham are contained in Exhibit 16, are they not?
A. You keep, you keep calling the, you keep calling the diagnosis as findings, and the --
Q. Well -- okay, go ahead.
A. And the findings are in the body of the report. This report speaks for itself on the body of the report.
Q. Let me put it this way. The findings that you have recorded here of Dr. Graham, they're not

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anywhere in his operative report, are they?
A. No, the findings described by Dr. Graham, which is the bowstringing, which is the tape that he was able to feel, and that's exactly what I'm referring to, were the result of the relaxed pelvic floor. That's my explanation on this document.
Q. But that --
A. I haven't finished answering your question. The findings, the findings described by Dr. Graham specifically, the bowstringing and the sensation of the tape on the vagina, which was not without being exposed, is a result of all this, of all these problems, the damaged and relaxed vaginal floor, three previous vaginal deliveries, and the findings that he described of granulation tissue is exactly what he describes.
Q. Except he doesn't say anything near what you're saying, does he?
MS. GALLAGHER: Object to form.
BY MR. FREESE:
Q. He doesn't conclude anything like what you concluded, does he?
MS. GALLAGHER: Object to form.
A. It's a, it's a different, it's a different, it's a different description, because what

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he is saying is that his impression is that the tape is causing the pain. What the findings that I am talking about is about the bowstringing of the tape.
BY MR. FREESE:
Q. And he found the bowstringing, right?
A. He did describe that before surgery.
Q. And he did not believe that the bowstringing had anything to do with the avulsed levator muscle, did he?
MS. GALLAGHER: Object to form.
A. No, he did not contribute to that, he did not describe that.
BY MR. FREESE:
Q. You did.
A. I did.
Q. Dr. Sepulveda, have you looked at any of the manufacturing defect reports that Ethicon generated off of the lot that Jennifer Ramirez's mesh came from, that her sling came from?
A. No, I have not, I have not seen specifically the manufacturing defects from that specific lot.
Q. Have you investigated that?
A. I, I did see it on the TVTO company documents, I saw a picture of, of particles in one of

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the, one of the slings.
Q. You think it was simply one sling that was suffering these particle loss problems?
MS. GALLAGHER: Form.
A. I don't know how many of them were, were reported.
BY MR. FREESE:
Q. Well, what if it was one versus a hundred, would that make a difference to you?
A. Well, you just asked me a question if I knew how many of them, and my answer is no, I don't know how many. One or a hundred, I don't know.
Q. You're trying to give an opinion that there was not particle loss on Jennifer's sling, are you not?
A. Yes.
Q. Yet you have no idea how many slings from that lot were suffering excessive particle loss, do you?
A. I can only base my opinion on what the implanter described, and the implanter described there was no particle loss.
Q. He did not see any?
A. He did not see particle loss.
Q. And, therefore, you concluded there was

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none?
A. He is in a privileged position to, to judge if there are particles.
Q. Just answer my question. Just because Dr. Reyes didn't report it, you concluded there was none in Jennifer, is that correct?
A. I can safely conclude because the implanter did not see any particle loss, that there are no, no particles.
Q. And you are not here to give an opinion whether or not that lot was defectively manufactured in contravention of Ethicon's standards, am I correct?
MS. GALLAGHER: Object to form.
A. I don't know if they define -- I do know, I do know that they define one specific standard, which was a number of particles which I cannot recall at this time.
BY MR. FREESE:
Q. It was five.
A. But I can tell you that if there's, if it's one, five or ten, the best person to say that is Dr. Reyes.
Q. Okay, well, that's not my question. You have not investigated what Ethicon did in reviewing the lot of mesh that went into Jennifer's sling, am I

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correct? Her TVTO sling?
A. I am aware that there were communications, which I have read through, but since most of my input has been concentrated on this, I cannot recall. On the, I should have to say on the clinical summary and the opinion, I cannot recall of one specific article that I can pull to you and show.
Q. Will I find it in the TVTO company documents?
A. It might be there.
Q. Well, you say that reported particles in a blister pack from one of 992 devices in the same lot.
A. I probably read it in the company documents.
Q. Okay, and you believe that they only found one pack with particles in it?
A. That's in my -- where is it in my report?
Q. Let me just short circuit this. You're not offering any opinions, good or bad, about manufacturing defects in this case, are you?
MS. GALLAGHER: Object to form.
A. It depends on what area of manufacturing. I can tell you that if it was manufactured one way or the other, I cannot give an opinion on it, because I don't manufacture slings, of course. I want to stay

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truthful to what I testify on, but as an issue of the particle loss, the implanter is the best person to see.
BY MR. FREESE:
Q. I understand that, but you have not investigated informed, scientifically valid opinions whether or not the manufacturing processes were followed according to the manufacturer's specifications in this lot that included Jennifer's sling, am I correct?
A. I have not done an investigation on it, no.
Q. I'm going to page 61. I don't know what page it is on your report. It starts off with Ms. Ramirez's source.
A. Yes.
Q. You say Mr. Ramirez's source of periodic dyspareunia, if present before Dr. Zimmern's surgery, was caused by abnormal healing into the vaginal excision from the hysterectomy, unrelated to the TVTO. Additionally, after the hysterectomy, the avulsed levator muscle on the left resulted in the upper part of the vagina becoming detached and the vaginal vault scarred which resulted in additional complaints of dyspareunia. Do you see that?
A. Yes.

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Q. So, let's go to the next paragraph, the diagnosis --
A. Here, yeah, Mrs. Ramirez's source, yeah, I got it.
Q. And we've already talked about that, right? You've given me all your opinions about the avulsion of the levator muscle on the left resulted in the upper part of the vagina becoming detached and the vaginal vault scarred?
A. It is my opinion to a reasonable degree of certainty that Mrs. Ramirez's source of periodic dyspareunia, if present before Dr. Zimmern's surgery, was caused by abnormal healing into the vaginal incision from the hysterectomy unrelated to the TVTO.
Q. Okay, so let's stop. You're the only doctor that's made that diagnosis, correct?
A. No, that's, there was, there was a diagnosis by Dr. Atkerson about dyspareunia on deep penetration.
Q. But my question, Dr. Sepulveda, you were the only doctor that has said that her periodic dyspareunia was caused by abnormal healing from the hysterectomy, correct?
A. Yes, that is my opinion.
Q. And you're the only one that holds that

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opinion?
MS. GALLAGHER: Object to form.
A. I'm the one giving that opinion, yes.
BY MR. FREESE:
Q. But no treating physician of Jennifer holds that opinion, correct?
MS. GALLAGHER: Object to form.
A. No, no treating physician is holding that opinion.
BY MR. FREESE:
Q. Additionally, after the hysterectomy, the avulsed levator muscle on the left resulted in the upper part of the vagina becoming detached and the vaginal vault scarred which resulted in additional complaints of dyspareunia. Do you see that?
A. That is my theory of how this happened.
Q. I understand, and your theory is that in addition to the hysterectomy, the avulsion of the levator muscle is also contributing or causing her dyspareunia, correct?
A. Yes, I believe there's a complex etiology here in which the predisposing factor was an avulsed levator, the lack of support at the pubocervical fascia produced this, this vaginal wall to come down and it allowed for the bowstringing to be felt.

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Q. And you would agree with me that you're on the only doctor that has that opinion, correct?
A. Yes, I am the only one that has given that opinion so far, to my knowledge, yes.
Q. And you're saying that her levator avulsion is causing in part or whole her dyspareunia?
A. No, I think that her dyspareunia is caused also by the hysterectomy.
Q. I understand. I said in part.
A. Well, levator avulsion by itself may be a less frequent cause of dyspareunia than a hysterectomy.
Q. I'm not quibbling with you, Doctor. You believe that the avulsion of the levator muscle is one of the things that may be causing her dyspareunia?
A. It is a predisposing factor to it.
Q. Okay, and you are the only doctor that has expressed that diagnosis, correct?
A. That is correct.
Q. Does an avulsion of the levator muscle cause scarring?
A. Yeah, there's a scar actually on the detached muscle.
Q. And you've identified it in your examination?
A. Yes, that was described on this area with

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fibrotic tissue.
Q. You're saying it was described by you?
A. No, it was described I believe on the MRI report.
Q. But not as a result of a levator avulsion?
A. No, not as a result of a levator avulsion.
Q. Does anyone say that a levator avulsion caused scarring other than you?
A. No, it's, if you detach a muscle, as you would any muscle that you would detach from its attachment, it will form a scar.
Q. Has anyone said that scarring occurred in Jennifer's pelvis because of a levator avulsion?
A. No.
Q. Okay. Let's drop down. You see where it says it's my opinion to a reasonable degree of medical probability and certainty that the operation performed by Dr. Zimmern was not medically necessary or appropriate?
A. Yes.
Q. I guess we can agree that, that opinion is that Dr. Zimmern has committed medical malpractice, correct?

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A. Yes.
Q. Because performing any medical procedure that's not medically necessary is by definition malpractice, is it not?
A. If it leads to the pains that the patient has, yes.
Q. Any surgery has pain, does it not?
A. Every surgery has a risk for pain.
Q. And any unnecessary surgery deliberately done is malpractice, correct?
A. I don't say it was deliberately done. I'm saying that it was unnecessary.
Q. Well, Dr. Zimmern deliberately did the surgery, did he not?
A. He performed the surgery. I don't know which state of mind he was when he did it.
Q. Are you saying he didn't know he was performing surgery?
MS. GALLAGHER: Object to form.
A. I'm saying I don't know in which state of mind he was when he decided to do the surgery.
BY MR. FREESE:
Q. But you understand he intentionally did the surgery he intended to do?
A. He intended to go and take the mesh out,

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yes.
Q. And it's your opinion that that was medically unnecessary?
A. That's my opinion.
Q. And that surgery would have been a violation of the standard of care?
A. That is below the standard of care based on the symptoms that the patient has had.
Q. And you believe that Dr. Zimmern, in doing this surgery, injured Jennifer's pudendal nerve, correct?
A. Yes.
Q. I want you to describe for me -- well, let's start with, so before Dr. Zimmern's surgery it's your opinion that Jennifer had not suffered a pudendal nerve injury, correct?
A. That is correct.
Q. You agree today that Jennifer does have a pudendal nerve injury?
A. That has been demonstrated by the effects of the pudendal block, yes.
Q. And it's an opinion you share, correct?
A. Yes.
Q. And it is your opinion that the sole cause of that pudendal nerve injury is the surgery

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performed by Dr. Zimmern?
A. Yes.
Q. All right. I want you to explain in much detail how Dr. Zimmern's surgery caused the pudendal nerve injury, please, sir.
A. The excision of, or the search for a sling that was nonexistent in the diagnostic studies led to a dissection that was extensive on that side, on the left side. That dissection showed that there was periurethral fat. Periurethral fat in the anatomic dissections is not a common finding. It is my opinion that the fat that was obtained on the dissection and described by Dr. Zimmern in his operative report comes from the ischioanal fossa.
Q. Okay, the fat that he found in his surgery was actually ischioanal fossa?
A. From the ischioanal fossa, yes.
Q. What, what surgical instrument was he using that caused the pudendal nerve jury?
A. It's just the dissection. You can go with your finger and do a dissection in that area, and that can produce an injury to the pudendal nerve.
Q. What do you believe based on your review of the records? I mean, you're accusing the man of malpractice, so I'm just curious, did he do it with his

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finger? Did he do it with a scalpel? Did he do it with scissors? What device did Dr. Zimmern use to cause this pudendal nerve injury?
A. It's the dissection with the finger.
Q. Okay. So a finger dissection caused the pudendal nerve injury.
A. That's one of the factors, yes.
Q. So, did he basically have to get his finger on the pudendal nerve?
A. You know, what happens is, when you have a levator muscle that is detached and you already have an area that has been injured over time, you go into that area and there's very little muscle that you can feel. You're not actually looking at it, you're actually feeling for it. So, when you do all this, all this dissection, you injure the area, because this is not a pudendal nerve injury that has provoked, as many of your, as more than one of your experts has said, has provoked anal incontinence or has provoked urinary incontinence. This is an irritation to the pudendal nerve and this irritation to the pudendal nerve is what really ended up producing more pain. Before that, there was no injury on the dissection.
Q. And --
A. There was no injury to the nerve, I

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should have said, there was no injury to the nerve.
Q. How far did he dissect?
A. It's, by the time you get into the ischioanal fossa, you have no levators protecting you. All you have to do is two, three centimeters, and you can ream that area.
Q. Does your opinion that Dr. Zimmern caused a pudendal nerve injury depend on the accuracy of your conclusion that she had a levator muscle avulsion?
A. It's a, it's a, it's a group of things that lead me to believe that this was injured at that point.
Q. Answer my question, Dr. Sepulveda. Does your opinion that Dr. Zimmern caused a pudendal nerve injury depend on the accuracy of your diagnosis that she had an avulsion of her levator muscles?
MS. GALLAGHER: Object to form.
A. It depends, it relies on the history of how a pudendal nerve is injured, it relies on the dissection and a search for a sling that was not there, a piece of sling that was not there. It also relies on the MRI diagnosis of the muscle coming down, and it relies on the, on the description of the, of the operator.
BY MR. FREESE:

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Q. Dr. Sepulveda, what I'm trying to find out, if we're proven that she did not have an avulsion to the levator muscle, if the jury believes that she does not have such a condition, would you still believe that Dr. Zimmern's surgery caused the pudendal nerve injury?
A. I see no other way to reach the pudendal nerve but by getting into this space where the fat is.
Q. I understand, but what I'm saying is does the avulsion have to exist in order to get the pudendal nerve?
A. No, you can get a pudendal nerve injury without an avulsion, but, again, as we have seen, there are contributing factors and there are precipitating factors and there are causative factors on here, and this is not just about a black-and-white situation, this is a situation in which the patient already showed that she had a defect on the left side, there has been pain before that, but there has not been neurological pain.
Q. Move to strike. That's not responsive to my question. Is it your testimony, Doctor, that the, the mesh that extends into the, beyond the obturator foramen is not still present in Jennifer today?
A. There's a definition, we defined that

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this morning, between the obturator space and the obturator foramen. The obturator foramen, the way we all know obturator foramen, the way it's described on anatomic books is in the retropubic space. That's different from the obturator space. We defined already that the sling follows a trajectory which is 1.5 to 2.5 centimeters from the obturator foramen. The fact that Mrs. Ramirez, I apologize myself for being graphic on this, the fact that she was able to use a vibrator, it virtually excludes a neurological injury. You cannot have a neurological injury constant in that area and vibrate and not feel pain with it, and the description of her pain was on deep penetration. So it is my conclusion that there was, if there was a mesh in there, it's not around the nerve.
Q. And I appreciate you volunteering that, but my question is, is there not residual mesh on her left side in her obturator space today?
A. There's nothing in the periurethral. Dr. Zimmern could not find mesh there.
Q. Not my question, Dr. Sepulveda. Is there synthetic TVT, polypropylene, Prolene mesh in her obturator space today?
A. In the --
Q. On the left side.

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A. On the obturator space, yes.
Q. So, the fact that Dr. Zimmern didn't find any mesh on the left side doesn't mean there wasn't any mesh on the left side. We both agree that even after Dr. Graham's revision, there remained part of the TVTO in her obturator space on her left side, correct?
A. There is mesh --
Q. Can we agree with that fact?
A. If we go to the left side, we need to make a, a specific of looking at the left side, on the medial aspect of the descending --
Q. The answer to my question is yes, Mr. Freese, there's still remaining mesh on her left side, on the other side of her obturator internus muscle, right?
A. Yes.
Q. What alternative causes did you consider and rule out for the injury to the pudendal nerve?
A. I find no other, no other things that could have injured the pudendal nerve. Now we do know that pudendal nerves can be injured in a variety of procedures, but the onset of the pudendal nerve symptoms after this, after this exploration is what leads me to believe that it was during this surgery.
Q. Okay, so is the fact that you think she

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did not have evidence of nerve injury until after Dr. Zimmern's surgery, that's the sole basis of your opinion that you can rule out everything else?

MS. GALLAGHER: Object to form.

A. Yeah, there's no evidence of a pudendal nerve injury before that surgery.

BY MR. FREESE:

Q. Can synthetic mesh cause a pudendal nerve injury?

A. Not, not in that, not in that distance. For a pudendal nerve to be injured, it's, it would have to be close to the pudendal nerve.

Q. Dr. Sepulveda, can synthetic mesh cause a pudendal nerve injury?

A. Are you talking about a synthetic mesh for a sling? Please clarify.

Q. Yes, for a sling.

A. A sling procedure. Yes, it has been described to cause a pudendal nerve when the TVTO has been improperly inserted.

Q. So, only an improperly inserted sling can cause a pudendal nerve injury?

A. Yes.

Q. And, so, did you consider maybe my initial conclusion was wrong, maybe Dr. Reyes put it in

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wrong, because an improperly inserted TVT can cause a nerve injury; did you consider and exclude that as a reason?

A. No, because she did not have a pudendal nerve symptomatology after Dr. Reyes' insertion of the TVTO.

Q. Well, she wasn't tested for it, was she? She had complaints of pain radiating down her leg, did she not?

A. The pain to the pudendal nerve, or injury to the pudendal nerve is not characterized by pain going down the legs producing tingling on the toes.

Q. In other words, you're saying that a pudendal nerve injury wouldn't mimic a sciatic nerve injury?

A. It does not mimic a sciatic nerve injury.

Q. And you've never seen any literature that says that?

A. I think that if you, if you take the pudendal nerve at the very end and you get an actual pudendal transection, it could, it could have a potential of mimicking, but once you establish a diagnosis that it's traditional pudendal nerve, it's separate from a sciatic nerve.

Q. Let's be clear here. You testified

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already today that you have never seen a pudendal nerve injury caused by a revision to a sling, have you?

A. I have not seen that either.

Q. All right. But you know that meshes are reported to cause pudendal nerve injuries, the mesh themselves?

A. That's, I think you're referring to, to the, when it's placed on the side of the pudendal nerve. I don't think that there's a report of a TVT, or there are few reports based, there's a Paulson study, which is a case report, there is the Masata, which is also case reports, but there's no actual cohort study that have measured pudendal nerve injuries after a TVTO.

Q. I'm just talking about synthetic meshes generally. You don't think that mesh can cause -- strike that.

Your opinion, Dr. Sepulveda, is that an improperly placed synthetic mesh can cause a pudendal nerve injury?

A. That would be the case, yes.

Q. And you concluded that that wasn't the case here because she wasn't showing, in your view, signs of a pudendal nerve injury before Zimmern's surgery, correct?

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A. Yes, I would have to speculate on that, even on the, the opinion about the TVT causing a pudendal nerve injury, the corona study, they actually write a sentence saying we speculate that this is what's causing it.

Q. I'm not sure what that's responding to so I'll move to strike. And if Dr. Zimmern's surgery in fact caused a pudendal nerve injury, it will be the first time in the history of your practice as a doc you've ever seen it, correct?

A. Yes. That would be the first time that I see it described beyond what has, for an explanting, explanting surgery.

Q. Okay. This would be the first time in an explant surgery that you've ever seen, heard, reported anything, where a pudendal nerve was caused by that, is Dr. Zimmern's surgery on Jennifer?

A. The first explanting surgery, I'm not aware of any report, even case reports of an explanting surgery for TVT causing a pudendal nerve injury.

Q. And you've done three in your life, maybe?

A. Excisions?

Q. Yes.

A. Yes, I don't take many slings out.

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Q. Do you have any idea how many revision surgeries Dr. Zimmern has done?
A. No, I can not count that.
(Plaintiff's Exhibit No. 23 was marked for identification.)
BY MR. FREESE:
Q. Let me show you Exhibit 23, sir. Have you ever seen article this before, sir?
A. No, I have not seen it before.
Q. This is an article by Doctors Hibner, Castellanos and Desai. Do you see that, they're doctors at Division of Surgery and Pelvic Pain at Creighton University School of Medicine and -- you see this?
A. Yes, I do see the article. I have not read the article, though.
Q. Let's start on, where it says introduction. It says pudendal neuralgia was first described in 1987 by Amarenco. It is a severely painful and disabling neuropathic condition affecting both men and women. Do you see that?
A. Yes.
Q. Do you agree with that?
A. Well, that's what it says here.
Q. It says pudendal neuropathy yields, when

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they searched pudendal neuropathy, they got 115 publications. It says few of them discuss diagnosis or treatment. Still, this syndrome is often unrecognized by a majority of physicians, including physicians experienced in pelvic pain, such as gynecologists, urologists and neurologists. Do you see that? You agree with that?
A. Well, I would need to read the whole article, Mr. Freese. I've never read this article before. But if you wanted me to give you an opinion on it, you could have forwarded it to me before today.
Q. Well, I'm just showing it to you now, because you're giving an opinion, you're the expert on behalf of Ethicon for this pudendal nerve injury, are you not?
A. I'm an expert for TVTO. The pudendal nerve injury is something that came after recent findings.
Q. I understand, but you're the witness designated by the company as the urogynecologist to testify about it, correct?
A. Yes.
Q. All right. Are you an expert on pudendal nerve injuries or not?
A. I don't think that there is such a thing

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as an expert. I think that pudendal nerve injuries, being as rare as they are, not even the best attempt of defining a criteria has been successful.
Q. I'll accept that. So you don't consider yourself as an expert on pudendal nerve injury because you don't think anyone exists, correct?
MS. GALLAGHER: Object to form.
A. Well, I'm an expert on pelvic floor, I'm an expert on female pelvic medicine, and that qualifies me to give an opinion about the pudendal nerve.
BY MR. FREESE:
Q. Well, we'll see about that. Let's look on the symptoms page. It's the third page, sir.
A. Yes.
Q. You see it says patients with pudendal neuralgia are often diagnosed with interstitial cystitis, vulvodynia, dyspareunia, and persistent sexual arousal. Do you see that?
A. Yes.
Q. Do you agree with that?
A. Yes, I would say that that's, I would understand that, yes.
Q. Did you ever make any finding that Jennifer was, had any kind of case of interstitial cystitis?

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A. No.
Q. What about dyspareunia?
A. Dyspareunia, it's a complaint that she has had.
Q. Okay. And the literature says that is oftentimes what is diagnosed in patients when they actually really have pudendal nerve injury, correct?
A. Yes.
Q. All right. By the way, Doctor, before you formed your opinions about pudendal nerve injury, did you do a thorough literature review in order to satisfy yourself that you knew enough to give an opinion about pudendal nerve injury?
A. No, I rely on the diagnosis of pudendal nerve injury on the exam of Dr. Kelly Scott.
Q. So just take her diagnosis of pudendal nerve injury; you didn't do a literature search and attempt to satisfy yourself what all the literature says about pudendal nerve injury and what causes it, correct?
A. No, before she made the diagnosis with all the whole extent of the records that I saw, there was no indication of a pudendal nerve injury.
Q. That's not what I'm asking you. In formulating your opinions, you haven't even done a

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search of the pudendal nerve injury databases and found out what the literature is out there on pudendal nerve injury and what if any connection there is to synthetic mesh, is that fair?

A. Yes, I did do a PubMed. Once I saw that there was a finding, I went to PubMed and checked for papers about pudendal nerve injuries.

Q. And you didn't find Exhibit Number 23, did you?

A. No, because it has no description of a TVTO.

Q. So the only thing you searched was pudendal nerve TVTO?

A. Yes, I wanted to know if that was associated to it. I wanted to know if hysterectomy could be associated to it. I wanted to know if any other procedures done for incontinence could be associated to it.

Q. How about typing in mesh, synthetic mesh and pudendal nerve injury, did you do that search?

A. No, that would be an inaccurate search because that does not define meshes for urinary incontinence. That search would be inaccurate.

Q. Well, that's how I found in this article. I typed in synthetic mesh and pudendal nerve, and this

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article was the first one that popped up, and you're saying you didn't find it because that would have been wrong to search for synthetic mesh and pudendal nerve injury?

A. Yes, that's an inaccurate search. You have to look for sling, midurethral slings, TVTO, any other sling. Incontinence procedure.

Q. All right. And if you look at cause for pudendal neuralgia, do you see that?

A. Yes.

Q. It says pudendal neuralgia may arise from five distinct mechanisms. First, there may be a direct injury to the nerve. Second, pelvic floor muscle spasms or pelvic floor tension myalgia may cause compression of the nerve. Third, pelvic floor muscle alone, without pudendal neuropathy, may also mimic pudendal neuralgia symptoms, and fourth, biochemical injury from infection or disease. Finally, there may be compression of the spinal cord nerve roots. Do you see that?

A. Yes.

Q. Do you agree first of all that those are the five distinct mechanisms that cause pudendal nerve injury?

A. That's listed as it may arise. So the

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fact that it's described as may, not as causes, does not limit the, that to those causes. To those five distinct mechanisms.

Q. Do you agree that at least those five distinct mechanisms?

A. That's one of the five mechanisms of the whole spectrum of the universe.

Q. Which one of these would Jennifer's pudendal nerve injury caused by Dr. Zimmern fall under?

A. It's the dissection.

Q. Which one of these five categories?

A. Oh, this doesn't list a surgery. I'm going to tell you why they don't list surgery, because this is about myalgia, this is about neuralgia, and there is a difference between neuropathy and there is a difference between neuralgia.

Q. Well, you know, the article actually addresses that and says they're essentially used interchangeably. So what is the difference between neuropathy and neuralgia?

A. To be diagnosed as a neuralgia, you have to have it in all the branches, and neuropathy is just in any of the segments. That's why you see in here that it doesn't define for neuropathy or neuralgia in this specific area. I'm going to explain that better

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in a second. These are five possible causes. If you're looking at the cause of irritation on this pudendal nerve, it has to be the dissection. There was no pudendal symptoms before her surgery.

Q. Move to strike. That's not my question, Doctor. Are you telling me that this article that identifies five distinct mechanisms, none of which applied to Jennifer as a cause of pudendal nerve injury, correct?

A. There are other factors in here. It could be direct injury by palpation.

Q. That's what I'm saying. I was giving you the chance. Are you saying that the direct injury by Dr. Zimmern's finger dissection caused the pudendal nerve injury, that's what you're saying, right?

A. That could cause that, yes.

Q. Would that be under the category of a direct injury to the nerve?

A. Yes, could be a direct injury to a nerve.

Q. Okay. And if you look down, it says, quote, "Permanent compression of the nerve is caused by adhesions or foreign bodies such as mesh or suture entrapping the nerve." Do you see that?

A. Yes, but we know that there's no mesh entrapping this nerve.

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Q. Hold on a second. How do you know that?
A. Because there was no report on her neurography report.
Q. Have you looked at Dr. Eickoff's report?
A. I saw his report, yes, I saw his slides.
Q. Did you see any nerve entrapment reported in his report?
A. No.
Q. I'm not asking you if you saw it, do you know whether Dr. Eickoff reported nerve entrapment?
A. No, he did not report nerve entrapment. He report a nerve growing around the, around the scar.
Q. Permanent compression of the nerve is caused by adhesions or foreign bodies such as mesh or suture entrapping the nerve. Do you see that?
A. Yes.
Q. That cites an article, Fisher, Lotze, Nerve Injury Locations During Retropubic Sling Procedures, International Urogynecologic Journal, Pelvic Floor Dysfunction. Did you find that article?
A. Yes.
Q. You have seen that article before?
A. I see that.
Q. Okay. If you look down at causes of pudendal neuralgia -- first of all, do you dispute that

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Jennifer has pudendal neuralgia?
A. No, she described the pain that was alleviated by a block.
Q. Okay. So you agree Jennifer does have pudendal neuralgia?
A. I agree with Dr. Kelly Scott's diagnosis.
Q. That she has pudendal neuralgia?
A. Yes.
Q. Okay. According to this article, see where it says table, causes of pudendal nerve neuralgia? What is the very first thing that the authors identify as the cause of pudendal neuralgia?
A. They list pelvic surgery, especially with the use of mesh.
Q. And you didn't know that before I just showed you that article, did you?
A. No, because I had not read the article. I have not read this article.
Q. Did you have to read this article to know that the number one cause of pudendal neuralgia is pelvis surgery, especially with the use of mesh?
A. How could I give you an opinion about this article? I have not read the article, I have not confirmed the bibliographies on the back. You're essentially showing me this, which is supposed to be an

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article, and i haven't read it, I haven't confirmed it.
Q. You might have seen it in another article.
A. No, I don't see it.
Q. So, this is the first time that you've seen authors published saying that the number one cause of pudendal neuralgia is pelvic surgery, especially with the use of mesh?
A. Yes, I don't see, I don't, I haven't read this article, I cannot give you an opinion on this article.
Q. So, I'm showing you an article on pudendal neuralgia. It's an opinion you hold in this case and you can't comment on this article because you've never seen it, correct?
A. It's an article that I have not read.
Q. I know, I'm saying you can't even comment on it because you never read it before, correct?
A. I cannot comment on this article.
Q. Now, are you familiar with a Nantes criteria?
A. Yes.
Q. Okay, and the inclusion criteria for pudendal nerves, if you turn to the next page you'll see that. You see the inclusion criteria?

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A. Yeah, that's the Nantes test criteria.
Q. And you're familiar with that?
A. Yes, I am aware of how it was done.
Q. All right. Pain in the area enervated by the pudendal nerve. Jennifer has that, correct? She has pain in the area enervated by the pudendal nerve.
a. In one of the segments.
Q. So, she has that. Pain more severe with sitting. She has that, does she not?
A. Yeah, actually I have searched on that pain when she was sitting, and there is no description before her surgery that she required to sit on any type of cushion. The only time that she had described that she had to sit on a cushion was afterwards.
Q. Was after the Zimmern?
A. After her explanative surgery.
Q. You agree she meets all the Nantes criteria?
A. No, I do not agree because there's testimony on Dr. Kelly Scott's deposition that pain that does not awaken patients from sleep is not a criteria that she has.
Q. So she's got four of the five, which in Dr. Scott's opinion was enough to include her and diagnose her with pudendal nerve injury, correct?

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A. Yes, and this is the situation that we find with a Nantes criteria. This is a criteria that is not based on evidence, it was put together on a weekend in September of 2006, two days. That's what they took to come up with the criteria.
Q. So you're criticizing the Nantes criteria?
A. Yes, I am.
Q. Will I find that anywhere in your report, that you criticize the inclusion criteria?
A. When I look at the --
Q. Just answer my question, Doctor. Will I find in your report anywhere your criticism of the Nantes criteria?
A. No, you will not find it in the report.
Q. Now, would you look at the associated signs for pudendal neuralgia?
A. Yes.
Q. Referred sciatic pain, do you see that?
A. Yes.
Q. Tell me how referred sciatic pain would be described by a patient.
A. The patients describe pain as the sciatic nerve.
Q. I know, but if I was describing sciatic

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pain, how would I describe it?
A. It's a pain that comes through the back and goes down.
Q. Down the leg?
A. Down the leg, yeah.
Q. Just the way Jennifer reported it, correct?
MS. GALLAGHER: Object to form.
A. No, she reported the pain to be in the front, to the medial aspect down the leg.
BY MR. FREESE:
Q. And you think she's not reported what, from a layman's standpoint what would be described as sciatic pain?
A. Not as typical sciatic pain, no.
Q. Okay. Urinary frequency with full bladder. Does she have that?
A. There's no urodynamics to confirm that.
Q. Well, does she report urinary frequency with a full bladder, yes or no?
A. She feels she does not empty completely.
Q. I'm talking about frequency.
A. I don't recall her frequency is with a full bladder, there is no description of that.
Q. She reports frequency all the time,

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doesn't she?
A. She has reported urinary frequency, just that it has not been with a full bladder like you just represented.
Q. Dyspareunia or pain after intercourse. Do you see that?
A. Yes.
Q. She reported that since way before Dr. Zimmern did his surgery, did she not?
A. She reported dyspareunia actually before Dr. Reyes' surgery.
Q. Doctor, listen to my question. She reported dyspareunia and described it as pain after intercourse, did she not?
A. I don't recall the pain after intercourse. I do recall the dyspareunia.
Q. Will you at least defer to her in her deposition if she said that she described part of the dyspareunia as pain after intercourse?
A. I would defer to her description.
Q. And you wouldn't dispute that, correct?
A. I would not dispute her description.
Q. And you agree that me that's an associated sign of pudendal nerve injury, is it not, that is dyspareunia or pain after intercourse?

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A. I agree that this is disclosed in this article here.
Q. And you will agree with me that she reported it in her deposition and reported it in medical records prior to Dr. Zimmern's surgery, correct?
A. She reported dyspareunia before her explant surgery, yes.
Q. And reported dyspareunia after sex before Dr. Zimmern's surgery?
A. I just answered that, I don't recall that.
Q. If she said it, then you accept it?
A. I would have to defer to her. I just said I would defer to her.
Q. Thank you. Now, Doctor, am I correct that your reference point in determining the cause of the pelvic pain is always that it cannot be caused by the mesh because it's your opinion that it's always the mesh itself cannot cause pain?
MS. GALLAGHER: Object to form.
A. Yes, the mesh itself don't cause, don't cause pain.
BY MR. FREESE:
Q. But that's an opinion you hold across the

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board no matter what woman you're looking at, it is the opinion of Jaime Sepulveda that mesh cannot cause pain, you go into your differential diagnosis holding that opinion, correct?

MS. GALLAGHER: Object to form.

BY MR. FREESE:

Q. Just answer that question. Do you go into your differential diagnosis holding that opinion?

MS. GALLAGHER: Object to form.

A. Well, I go into the differential diagnosis understanding that there is no evidence that just a single implantation of a mesh implant by itself, with no other procedures, would cause pain. And that's going to be, and I do understand that it's going to be a very difficult test to do and a difficult thing to obtain, it will require inference, so I do understand the limitations of the science in that.

BY MR. FREESE:

Q. Okay, and just so we're clear, if you're going to do a differential diagnosis, mesh causing the pain or mesh causing dyspareunia or mesh causing groin pain or mesh causing pudendal nerve injury, you're always going to find something other than mesh because you don't believe mesh can ever cause any of that anyway?

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MS. GALLAGHER: Object to form.

A. I would look at the whole patient. In other words, I would not just look at mesh as the cause because it's not as simple as just mesh causing pain.

BY MR. FREESE:

Q. I understand that, but when you do a differential diagnosis, you've already concluded that it doesn't cause it, so therefore it cannot be the cause of any complication that any woman suffers, correct?

MS. GALLAGHER: Object to the form.

A. If I can exclude all the other causes, I can rule out all the other causes, and the only one I'm left with is mesh, I will conclude that.

BY MR. FREESE:

Q. Okay, but you've always concluded it's never mesh because you hold the opinion it's always something else other than the mesh causing the complications?

MS. GALLAGHER: Object to form.

BY MR. FREESE:

Q. Fair?

A. I have found, I have found, I have found in almost every instance other causes of pain, and I find that on the cases that I review, and I also found

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that on the patients that are referred to me.

Q. One hundred percent of the time, you found something other than mesh causing an adverse complication?

MS. GALLAGHER: Object to form.

A. So far, is what I have seen.

BY MR. FREESE:

Q. And the reason you hold that opinion, Dr. Sepulveda, is because you don't believe that there's any science supporting the concept that mesh by itself can cause pain. Fair?

A. The reason why I hold, I hold this opinion is because when I look at the whole clinical picture, when I look at all the data that has been published and when I look at what has been published about mesh by itself causing pain, I cannot conclude, based on all the evidence that I have, that mesh by itself is what causes pain.

Q. Because you believe there's no science that says mesh by itself causes pain, correct?

A. Right, mesh by itself does not cause pain.

MR. FREESE: Let's take a break.

(Break was taken from 4:05 p.m. to 4:20 p.m.)

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MR. FREESE: We marked the thumb drive as Exhibit 15. The password for Exhibit 15 is capital S, Sepulveda 1234 exclamation point.

BY MR. FREESE:

Q. Dr. Sepulveda, back to your report. It is your opinion that Dr. Zimmern's surgery caused the pudendal nerve injury because he got into the ischiorectal fossa, that's what you were talking about, that's i-s-c-h-i-o-r-e-c-t-a-l, fossa, f-o-s-s-a, correct?

A. Yes, the ischiorectal fossa is also known as ischioanal space.

Q. And it's your opinion that Dr. Zimmern got his finger in the anal rectal space, or the anal fossa space?

A. Yes, on the dissection, if you have a patient that has very little fibers on the levators, you can easily get to that space.

Q. And it doesn't matter whether or not there was a levator muscle avulsion or not, he still could have gotten to the ischiorectal fossa with his finger, whether or not there was a muscle avulsion?

A. I believe that the muscle avulsion in that area just made it much more accessible.

Q. I understand, but could he have gotten to

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that space with his finger if it wasn't for a muscle avulsion?
A. Yes, I think it would be less likely for him to get there. You can always get there as, without an avulsion. When you dissect in cadavers and you get to that space from the obturator space, it doesn't always have a levator avulsion.
Q. So it doesn't matter whether or not there's an avulsion here in Jennifer or not, it's still Dr. Zimmern's finger in the ischiorectal fossa that caused the pudendal nerve injury?
A. Yes, there was, there was a manipulation of that space where the pudendal nerve sits that caused that injury. To what degree the levator avulsion contributed to it, that's why I can not give you a certainty.
Q. Okay. And am I correct that you have never seen a pudendal nerve injury caused by the way you're describing this in your career, correct?
A. No, I have not seen it.
Q. And you have never seen any literature describing a pudendal nerve injury being caused by a surgeon's finger going into the ischiorectal fossa?
A. No, I have not seen it described with an explantation surgery.

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Q. And it's never been described at a conference or a society?
A. No.
Q. There's been no case studies?
A. No reports of, of this, of an explantation causing pudendal nerve injury.
Q. So, if a jury is to accept the reliability that Dr. Zimmern's finger dissection caused the pudendal nerve injury, it would be the first time in medical history, in this world, that you know of, of that ever happening, correct?
MR. WALKER: Object to form.
A. It has not been reported, to my knowledge.
BY MR. FREESE:
Q. Listen to my question. It will be the first time in the medical history of this world that a pudendal nerve injury was injured by a surgeon's finger getting into the ischiorectal space during a mesh removal, correct?
MR. WALKER: Objection.
A. Yeah, that would be, that would be, there have been no reports, but whatever the jury decides obviously isn't up to me you or me, it's up to the jury.

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BY MR. FREESE:
Q. I understand, but if they decide it, they will be deciding something that you have never seen, that's never been reported, there's no study, there's no literature anywhere saying that a pudendal nerve injury can be caused this way, and they would have to accept for the first time in mankind known your opinion that the pudendal nerve injury was caused by Dr. Zimmern's finger. Correct?
MR. WALKER: Objection.
A. Either by his finger, or in the thousands of cases of TVTO, or in the few that has been resected, there has not been a reported pudendal nerve injury.
BY MR. FREESE:
Q. By a surgeon's finger?
A. By a surgeon's finger or an instrumentation during an explantation.
Q. You're saying finger, there's been no pudendal nerve injury ever caused by anything a doctor was trying to do in explanting a mesh?
A. Yes, but I can, I can tell you that the only person that knows what instrument was, was used ultimately would be Dr. Zimmern.
Q. That's what I asked you. You said your best opinion is it was his finger.

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A. That is my best opinion.
Q. Does it matter to your opinion whether or not it was a finger or an instrument?
A. No, no.
Q. If it was a finger or a blunt instrument, scissors, scalpel, it was the dissection into the ischio fat fossa?
A. Yes.
Q. That caused the pudendal nerve injury?
A. Yes. That irritated the pudendal nerve.
Q. And if Dr. Zimmern didn't get into the ischio fossa during his surgery, then your opinion wouldn't be reliable, would it? If it's concluded by the jury that neither his finger nor his blunt instrument or anything entered into that area, would you withdraw that opinion?
A. If the ischio -- and that's a very interesting question. If the ischioanal fossa was not entered, or the ischiorectal fossa, if it was not entered, then we'll have to look for other reasons why there was a pudendal nerve injury.
Q. Sitting here today, do you have any, is there an option B or are we only on option A?
A. No, I think, I think that there's, whenever you have something that happened after the

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surgery, always leads you to believe that it has do with the surgery. So, if it was, if it was something that caused this pudendal nerve injury before surgery, it should have been diagnosed before surgery.

Now, there is only one, one limitation to this, is that Mrs. Ramirez did not get to see Dr. Kelly Scott before her surgery.

Q. I mean, it is what it is. But, what I'm saying is, do you have -- what's the next likely cause if it wasn't Dr. Zimmern?

A. It was, it was the surgery that was done for the explantation. That's the most likely cause.

Q. I know, I said -- but you said if it turns out that he didn't get into that ischio fossa space, then you would have to look for the next option.

A. Which is something that happened before, but I have nothing to support an opinion on that.

Q. That's what I'm saying. It's either he got into the ischio fossa space and caused a pudendal nerve injury; if he didn't get into that space, then you don't have an opinion that his surgery caused the pudendal nerve injury, correct?

A. Right, that's what the, that's what the pudendal nerve is.

Q. And you would have no opinion to what

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caused it then after that?

A. No, I'm not aware of anything else causing it is afterwards.

Q. And so, if, if it, if it's proven or if you're satisfied that he didn't get into that space, by later testimony or later evidence, you don't have another theory or another opinion about what caused the pudendal nerve injury, correct?

A. No, I don't have anything else that could explain it, sir.

Q. Like the mesh, for example, that would never be your opinion?

A. Well, it's, the mesh is distant from the ischioanal fossa.

Q. Now, Doctor, am I correct that, in the time that you have consulted for Ethicon, that you have been paid in excess of a million dollars by them?

A. It's -- you mean over the last ten years?

Q. Yes, sir.

A. It may have amount to that, yes.

MR. WALKER: Before you go further, I do have a new version that looks more readable. Do you want me to email that to Tim?

MR. FREESE: Sure. It's Exhibit 7?

MR. WALKER: Yeah, well, it's the first,

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it's the tiny chart.

MR. FREESE: Yeah, you can go ahead and we'll substitute it as Exhibit 7.

BY MR. FREESE:

Q. Am I correct, Dr. Sepulveda, that in certain years that you have been paid in excess of $280,000 by Ethicon to provide consulting services?

A. I don't believe that that's, that that's accurate. It may have been now on the legal consultation, but not, not before.

Q. Well, how about in 2010, six years ago, you're saying you've never been paid more than $280,000 in that year by Ethicon?

A. No, they may have budgeted for that, but I don't believe that they paid me that amount of money.

(Plaintiff's Exhibit No. 24 was marked for identification.)

BY MR. FREESE:

Q. Okay. Let me show you what I've marked as Exhibit 24 to your deposition. Have you seen this document before?

A. Yes.

Q. Okay. It says from Ron Horton and to a number of people, subject, KOL usage. That's you, KOL, that's Key Opinion Leader usage, correct?

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A. Right.

Q. And if you'll look down, this is dated November 19th, 2010, correct?

A. This is November 19th, 2010.

Q. If you'll scroll down, you'll see Sepulveda total $288,400. Correct?

A. Sepulveda, 288, yes.

Q. And this is not a, like a budgeted contract amount. This is an email saying that, it's listing the highly used KOLs and the total they were paid this year. Do you see that in the first very sentence?

A. Yes, that's a, that says the contract amount.

Q. No, it doesn't. Sir, it says all, please see the below list of highly used KOLs, and the total pay they have received this year. Did I state that accurately?

A. Yes, but it says contract amount in the column on top.

Q. Sir, I'm not asking you to look at the column. I'm asking you to look at the sentence. It says the total pay they have received this year. That is an existing fact, isn't it?

A. No, that's what he says. I don't know if

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it's a fact.
Q. I understand. You don't have your 1099s with you, correct?
A. No, I don't.
Q. You've objected to producing those to us, haven't you?
A. Yes.
Q. They would show what you've been paid, correct?
A. No, they have other things on the 1099s.
Q. We would know from your 1099s what Johnson & Johnson had paid you, correct?
A. No, there are other, other incomes that I have.
Q. You're not listening to me, sir. I would know from your 1099s -- Johnson & Johnson sends you a 1099, correct?
A. They do send a 1099.
Q. And if I had your Johnson & Johnson 1099s, I would know what they paid you in each year.
A. I don't keep those, I just keep the tax returns.
Q. I'm not quibbling with you, Dr. Sepulveda. I'm just saying if I had them I would know exactly how much you were paid according to them,

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correct?
A. No, I don't think you would know that.
Q. Dr. Sepulveda, I know you may not agree with this, but according to them, in November of 2010, you had been paid $288,000, correct?
A. Yes, that's what it says.
Q. You don't agree that their records are accurate, correct?
A. I don't recall that number. It could be that number, by the way, it could be that number. I just cannot give you one way or the other if it was that number.
Q. Well, they say, and this is the only record I've got for that year, and it says you were paid $288,000. Correct?
A. Yes, that's what, the contract amount that it shows in here.
Q. What percentage of your entire income was it that year?
A. Probably 10, 20 percent, no more than, probably no more than 15.
Q. So, 288,000 was no more than 15 percent of your income in 2010?
A. Yes.
Q. And what other sources of income did you

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have besides Johnson & Johnson in 2010?
A. Well, I'm a partner at a surgery center, equal partner. I'm also the chairman of the board of that surgery center. I am a part owner of the diagnostic center. I am a shareholder in a management company with over 300 physicians. I am also a full partner in Vital M.D., which is the largest group of gynecologists in the country. Yeah, that's essentially what my income -- and my, obviously my medical-surgical practice where I, I work very hard.
Q. Doctor, has Johnson & Johnson ever made up more than 50 percent of your income in any year?
A. More than 50 percent?
Q. Yes, sir.
A. No.
Q. You got divorced in 2012, did you not?
A. Yes, I did.
Q. Do you remember signing an affidavit in your divorce saying that your income was $55,000 a month in 2012?
A. I don't recall that about my divorce.
Q. Well, I can have it pulled for you, but I'll represent to you that you signed an affidavit in 2012 saying your income was $55,000 a month. Can I rely on your sworn affidavit?

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A. On the, on my, for my divorce?
Q. Yes, sir.
A. Well, they calculated that.
Q. No, you signed an affidavit warranting and representing that your income in 2012 was $55,000 a month. Is that a true statement?
A. If I signed it, it must be a true statement.
Q. And if you were being paid $288,000 in a year, that's almost, that's almost $25,000 a month, it's more than $25,000 a month, is it not?
A. No, I don't, I don't, I don't believe that that's 55,000, but I also took bonuses. The income that I think you have is what I get from the office from my medical practice.
Q. No, sir, you represented the entirety of your income was $55,000 a month in your asset affidavit.
A. Okay.
Q. Do you stand by your affidavit that was filed in Dade County court?
A. Right. Yes.
Q. Okay, and it said $55,000 a month was your income in 2012.
A. I don't know, I haven't seen that. Do

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you have it?
Q. I do. I don't have a copy of it right now. I'll supply it to your lawyer, though.
MR. WALKER: We would make that request.
MR. FREESE: Sure. I'll be happy to do that.
(Plaintiff's Exhibit No. 25 was marked for identification.)
BY MR. FREESE:
Q. Let me show you what I've marked as Exhibit 25. Did you, in 2009, did you make $388,000 from Johnson & Johnson?
A. I don't know exactly what I made at that time.
Q. All right. Because we don't have the records, correct?
A. No, we don't have that.
Q. Look at Exhibit 25, and if you would turn to page, it's the second from the back, sir. You see where it says Sepulveda total, and goes to the left, $388,000?
A. Yes.
Q. Okay. So, in 2009, Johnson & Johnson is reporting payments to you of $388,000, correct?
A. That's the number that is written there,

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yes.
Q. And you have no reason to dispute that number sitting here today, do you?
A. There's -- let me see this report before I, I answer your question. So that's a contract amount. It is under the column of contract amount.
Q. Well, does the column say contract amount?
MR. WALKER: Yeah, it does.
BY MR. FREESE:
Q. All right, and how much were you paid in 2009 of the $388,000 contract amount?
A. I don't know.
Q. It says Arba payment. Do you know what Arba payment means?
A. No, I don't know that.
Q. You're not disputing that if you get a contract amount of 388,000, you were paid the full amount in 2009?
A. I may have been paid, I worked really hard through all that year.
Q. I'm certain you did, sir. I'm not disputing that. You're not disputing that you may have been paid $388,000, the full contract amount, in 2009, correct?

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A. I may have been paid that, but I didn't look into it.
(Plaintiff's Exhibit No. 26 was marked for identification.)
BY MR. FREESE:
Q. Okay. Now, let's look at Exhibit 26 to your deposition. Do you recall that, and you may not even know this, that you were one of the highest paid KOLs in 2009 and therefore, Johnson & Johnson put together some, some rules that your pay had to be approved by the top executives of the company, did you know that?
A. No.
Q. Do you know who Gary Pruden is?
A. No, I never, I don't recall ever meeting or knowing.
Q. Did you know he was, if not the, one of the top executives in Ethicon?
A. No, I didn't know that.
Q. All right, if you turn to the second page, you see where, December 22nd, 2009, it says, that your, Dr. Sepulveda's contract was submitted for $286,650 for the period of January 25th, 2010, through January 31st, 2011, which Gary verbally approved, do you see that?

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A. I see that.
Q. And you don't dispute that you were given a contract for $286,000 for calendar year 2010, correct?
A. I have no reason, no basis to dispute one way or the other.
Q. Do you think over 10 years you may be pushing $2 million from them?
A. No, I don't think so.
Q. I showed --
A. But I'm sure that you're, somehow you're going to find a way to calculate the whole thing, but I don't recall making that. All I know is that I work really hard, I do well on my practice, and I put every effort in everything I do, a hundred percent.
Q. I'm not suggesting you don't, Doctor, but I've shown you three documents in just three years that are pushing at a million dollars. So over 10 years you think you might be pushing $2 million?
A. I cannot testify one way or the other because I haven't looked into it.
Q. How about $10 million, do you think you might have been paid $10 million in 10 years?
A. No, I think I would have been retired if that was the case.

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Q. So you know it's not $10 million, right?
A. No, it's not.
Q. How about $5 million?
A. I don't think so, either.
Q. You're between 1 million and 5 million?
A. I don't, I don't think it could get close to 2 million. I, I may have made a million, which is what you say.
Q. Well, I've just shown you three years and it's a million, correct?
A. Yeah, those are very active years, very busy years.
Q. So, but it could be as much as 2 million but you don't think it's over 2 million?
A. Right, I don't think so.
MR. FREESE: I think I'm going to stop, Tim's got some questions, and I think we'll be done with Dr. Sepulveda.
CROSS EXAMINATION
BY MR. GOSS:
Q. Dr. Sepulveda, we've met several times before, but for the record I'm Tim Goss, and I also represent the plaintiff. I just have a few questions for you regarding the IFU.
A. Yes, sir.

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Q. First of all, do you intend to offer any opinions regarding the IFU from the TVTO?
A. My only opinion is my, my own use, and how it was used on the cadaver. That's the extent of my opinions on the IFU.
Q. So you don't intend to offer any opinions regarding whether the IFU adequately set forth the risks relating to the TVTO?
A. I have the reasons I explained there and we already went through that today. So I don't have any addition to it.
Q. You're not a regulatory expert?
A. No, I don't make a living or bill for regulatory advice.
Q. And I might be able to short circuit this. As I understand it, you may have some opinions as to what doctors look for in an IFU, but you don't have, you're not going to offer any opinions as to what the FDA or any regulatory outfit or what standards in the industry side are for what goes into an IFU?
A. I agree with that.
Q. Okay. Well, that's going to make this quick. Do you, from the doctor's perspective, does a doctor expect that the IFU will be fair and balanced?
A. Yes.

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Q. And does a doctor expect that the IFU will include those adverse risks that are reasonably associated with the product?
A. Yes, just the way you said it.
Q. Do you believe that if a company has two different products, that both do the same thing and have the same efficacy, but one has a greater risk than the other, that the company should only offer doctors that product with the less risk?
A. I think that, for each product, each doctor needs to be trained and each should be made aware of the details of the product.
Q. Okay, and I really don't want to hide the ball on this. I think you know where I'm going on this. I understand that you believe, it's your opinion that laser-cut mesh and mechanically-cut mesh have the same efficacy and have the same risks?
A. Yes.
Q. Okay. I want you to assume hypothetically for me that they have the same efficacy, but one has a greater risk profile than the other. Should the company only offer the one with the less risk profile?
A. I think that the risk profile needs to be defined. The surgeons using it need to research and

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then give, tell them this is what we have for, this is a set of our problems or advantages that we have with each one. Obviously we want to use whatever is more advantageous, in our hands, more for our patients.
Q. But if science reflects, the medical sciences reflect that the risks for one is greater than the other, shouldn't the company only offer the product that has the better risk profile?
A. There's, if it's well defined with medical science that there's one advantage of one over the other, I think the company will have to decide which one they're going to offer, because I don't see any surgeon using any, any product that have a higher risk profile except in those situations in which those surgeons say this doesn't apply to me and this will work better in my hands.
Q. If the company internally believed that the risk was greater for one than the other, wouldn't a reasonable manufacturer decide to only offer the product with less risk?
MR. WALKER: Object to form.
A. I believe that they may as well decide that, yes.
BY MR. GOSS:
Q. And as a doctor, you would hope that they

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would decide that?
A. I would, if, let's say that in the hypothetical scenario that they have a product that they decide not to, not to produce, I'll have the option of using what they give or go to another company that would offer me the product that I need.
Q. If there was a substantial -- strike that.
If there was a risk that was reasonably associated with laser-cut mesh that wasn't associated with -- strike that.
If there was a risk that was reasonably associated with mechanically-cut mesh that was not associated with laser-cut mesh, would the doctors expect the company to put that in the IFU?
MR. WALKER: Object to the form.
A. If that's something that's scientifically valid, yes.
BY MR. GOSS:
Q. And if the company internally believed that, would the doctors expect the company to put that in the IFU so that the doctors could make their decision?
MR. WALKER: Object to the form.
A. I would expect scientifically valid

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information from Ethicon or from any other company.
BY MR. GOSS;
Q. And if the company internally believed that the risk was greater for one than the other, the doctors would at least expect the company to put that in the IFU so the doctors could make their own decision?
MR. WALKER: Object to the form.
A. If they validate that information, yes. In other words, I don't want information from them that was not validated.
BY MR. GOSS:
Q. Well, you want to know what their internal opinions are, don't you?
A. I want to know what's scientifically validated.
Q. You don't care what their internal opinions are?
A. The dynamics that they may have between them is less important to me than the actual science behind it.
Q. Well, you would expect them to have science to support their opinions?
A. Yes.
Q. Do you plan to offer any opinions as to

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whether or not polypropylene mesh degrades?
A. I may be asked questions about it. I think I have testified already last week on, on, on the degradation of polypropylene.
Q. But you're not a polymer scientist?
A. No, I'm not a polymer scientist.
Q. And there are others that are more qualified than you to testify about whether or not polypropylene degrades?
A. I think that as a surgeon, there is a very limited information that we can give about degradation.
Q. And that would be including yourself?
A. Yes, we don't have that information one way or the other.
MR. GOSS: Thank you, Doctor.
CROSS EXAMINATION
BY MR. FREESE:
Q. Dr. Sepulveda, we were talking briefly about the particle loss. Remember the discussion we had about Jennifer's TVTO sling, and you said Dr. Reyes reported he didn't see any particles. Do you remember that discussion?
A. Yes.
Q. Is the phrase linting the same thing as

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particle loss in your mind?
A. Which?
Q. Is the word linting, l-i-n-t-i-n-g, does that mean the same thing as particle loss?
A. No, I don't have -- linting. I've never heard that term before to describe any particle loss.
Q. Have you ever even heard the term linting in connection with, with polypropylene mesh?
A. No.
Q. And in connection with mechanically-cut mesh versus laser-cut mesh?
A. No, I'm not familiar with that.
Q. What about the phrase denaturing, d-e-n-a-t-u-r-i-n-g?
A. No, I don't -- denaturing, I know chemically from my chemistry what denaturing is, but that's not as it relates to a sling.
Q. To the context of a sling, does the word denaturing mean anything to you at all?
A. No, it doesn't resonate as anything that I have read on the slings.
Q. And what about linting, does that resonate in your mind anything as it relates to mesh to you?
A. No.

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Q. And you've never described or had anybody describe to you particle loss as linting or denaturing?
A. Yeah, I don't have, I haven't heard any surgeon describing linting or denaturing.
Q. Can we agree that particle loss is an unwanted feature of a mesh? You don't want particle loss, correct?
A. It's, it's an unwanted feature, but it's something that it may appear with the, with the high pore monofilament that are needed.
Q. Do you have an opinion whether or not particle loss is clinically significant?
A. No, I don't have an opinion to base on that, how significant particle loss is.
Q. Okay. In other words, particle loss could be clinically significant or it might not be, you just don't know because you've never studied it?
A. In the surgical scenario, particle loss would be significant only if it reduces the actual length of my sling.
Q. Or increases the foreign body reaction, correct?
A. When you're talking about foreign body reaction, I would expect to, to see in an ultrasound or an MRI, with as good as a resolution as it is, I would

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like to see any reaction from a particle loss.
Q. I understand you'd like to, but my question is a little more simple. You don't have any opinions whether or not particle loss on TVTO or any midurethral sling is ever clinically significant, correct?
A. I don't have an opinion on clinical significant. Actually, I don't think it has been quantified. That's why I can't offer an opinion.
Q. And you've never seen any study by Ethicon trying to determine whether or not particle loss has any clinical significance, correct?
A. I'm not aware of any study correlating particle loss or foreign body reaction from the particle loss to the final outcome of a sling.
Q. Okay. And if there was a clinical significance to particle loss, you'd want to know about it, would you not?
A. I would like to learn about it.
Q. Doctor, do you remember meetings, Voice of Customer meetings at Ethicon?
A. That's a marketing term, Voice of Customers.
Q. You know what VOC means, Voice of Customers?

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A. Yes.
Q. And have you ever participated as the voice, as the customer in Ethicon meetings?
A. At some point they may have asked me and that's the way they would write it down.
(Plaintiff's Exhibit No. 27 was marked for identification.)
BY MR. FREESE:
Q. Let me show you Exhibit 27 to your deposition, sir. You see this memo, VOC on New Laser-Cut TVT Mesh?
A. Yes.
Q. And it's to Paul Parisi and Kevin Mahar, do you see that?
A. Yes.
Q. Do you know those men?
A. Yes.
Q. It says here qualitative one on ones on the topic the laser-cut mesh versus traditionally-cut mesh were completed the weekend of December 10 and 11 with several preceptors: Dr. Vince Lucente, Dr. David Robinson, Dr. Dennis Miller, Dr. Jim Raders, Dr. Bob Rogers, Dr. Jaime Sepulveda, Dr. Chip Hanes, and Dr. Aaron Kirkomo.
A. Yes.

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Q. Do you recall this meeting?
A. No.
Q. Okay. Laser-cut mesh was introduced in 2006, is that right?
A. I don't know.
Q. Do you know Allison London Brown?
A. I met Allison, yes.
Q. Okay. And who is she?
A. She, says here she is a program director. She was, yes, program director then.
Q. Do you know Paul Parisi?
A. Yes.
Q. Who is he?
A. He was I believe a liaison with physicians.
Q. And Kevin Mahar, who is he?
A. Kevin may have been a salesperson.
Q. All right. Do you see on the second page it says, quote, "denaturing/linting"?
A. Yes.
Q. Only four of the doctors to whom I spoke had previous personal issues with linting factor, but all expressed concern with it on behalf of other colleagues who may have experienced negative problems with it. Dr. Rogers made note that some peers may

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replace the first mesh if linting occurs, as they are concerned with leaving particles in their patient. Dr. Sepulveda said he had noticed the linting in patients after their next-day adjustment. All noted with some prompting that this was definitely a needed improvement. Do you see that?

A. Yeah, I don't know what she means by next-day adjustment or linting.

Q. Well, you were quoted by Allison London Brown as saying that you had noticed linting in patients. Do you see that?

A. Not only did Allison London Brown quoted me on next-day adjustment, which I have never, I don't know what next-day adjustment is, she spelled my name wrong, too.

Q. Okay. So, you don't deny being at this meeting?

A. I don't even know if I was at this meeting. I can tell you that this, this is not, I cannot remember and this is inaccurate.

Q. All right. It says denaturing and linting, correct?

A. I don't ever remember -- I don't use the term linting.

Q. Sir, the document says denaturing and

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linting, does it not?

A. Right.

Q. And it says Dr. Sepulveda said that he had noticed the linting in patients. First of all, had you ever noticed particle loss in patients?

A. I had seen one or two particles, yes, but it doesn't make a difference in my sling.

Q. I'm just asking, have you seen particle loss before?

A. Yes, I have seen particle loss before.

Q. Is that a wanted or unwanted event when you're placing a synthetic sling?

MR. WALKER: Objection.

A. That is a, that is an event that we used to recognize as part of the open weave meshes.

BY MR. FREESE:

Q. Now, you can tell from the context here that denaturing and linting is synonymous with leaving particles in the patient, correct? That's what it says?

A. No, I can not conclude this from that.

Q. It says Dr. Rogers made note that some peers may replace the first mesh if linting occurs, comma, as they are concerned with leaving particles in the patient. Do you see that?

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A. And I don't recall --

Q. I understand that, Doctor. Listen to my question. According to Allison London Brown, in a meeting you were at, Dr. Rogers was equating linting with particle loss, correct?

A. Yes.

Q. Okay, and she reports that you had noticed this linting in your patients, correct?

A. She records that I have seen linting.

Q. And says at the next-day adjustment, and you say that just never happened, you never reported this to Allison London Brown?

A. I don't use linting as a word.

Q. Sir, I'm just asking you, you never reported to Allison London Brown that you had seen particle loss in patients after their next-day adjustment?

A. I do not recall reporting this to Allison London Brown.

Q. Did she just make this up or lie or what?

MR. WALKER: Objection.

A. I don't even know what she did. I just tell you what I can tell you, that I don't recall ever mentioning this to her.

BY MR. FREESE:

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Q. She says all, so that would include you, right? All noted with some prompting that this was definitely a needed improvement. Do you see that?

MR. WALKER: Object to form.

A. Yes, I see that she writes that.

BY MR. FREESE:

Q. Do you agree that laser-cut mesh either solved or substantially improved the particle loss problem with mechanically-cut TVT mesh?

MR. WALKER: Object to form.

A. No, I think that they are two different products for the sling, but we recognize that as surgeons.

BY MR. FREESE:

Q. But my question is, Doctor, is, do you agree that after the introduction of laser-cut mesh, that it lessened particle loss that was seen with mechanically-cut mesh?

A. Laser-cut mesh have less particle loss than mechanically-cut mesh.

Q. And you knew it at the time that it was introduced, correct?

A. I, basically I saw that laser-cut mesh was a next generation of it.

Q. And, in fact, you participated as a voice

of the customer for Ethicon, did you not?
A. Well, that's what it says in this document.
MR. WALKER: Object to form.
A. I already told you I don't recall this.
BY MR. FREESE:
Q. Well, it says methodology included blind introduction of new material for panelists, initial reaction and follow-up questioning to understand overall acceptance of the new material, elasticity, memory, denaturing and linting. Do you see that?
A. Yeah, let me, let me read, let me read this, because there's no date on this.
Q. You know who has a date, don't you?
A. No.
Q. This guy right here. He can tell us a date. He can probably tell us right now from his laptop. I don't have a date, I'm just messing with you. I'd give you a date if I had it, but it appears to be in the year that laser cut was introduced. But you're welcome to look at the document.
A. I don't recall this thing, but to the best of my ability, and I'm obviously under oath, I don't recall this thing.
Q. But you don't dispute that it happened

and that there was a contemporaneous record of this meeting made, you don't dispute that?
A. Well, there was a record, I just don't know when this was, I don't recall using the term linting, and it's just not something that I use on my, on the time that I was with them.
Q. Last question. You see where it says memory, without prompting, several subject, paren, Lucente, Sepulveda, Rogers, Raders, Robinson, noted that the new material rebounded or bounced back and that this seemed unique over previous materials used, TVT or competition. Do you see that?
A. Yes.
Q. Does that accurately describe your view of laser-cut mesh versus mechanically-cut mesh in TVT?
A. I think that this is, this may have been one of those meetings in which they would give you one product and they would have you say what you feel with it, and, really, it's not a, there's not much science in it. Now, did I see particle loss? I think the essence of your question is, did I see particle loss that would make me shy away or stop using non-laser-cut mesh? No, most of the data on TVT and TVTO that I'm aware of is using non-laser-cut mesh. Do I see laser-cut mesh as the next generation of mesh? Yes, I

do see that.
Q. Okay. But that really wasn't my question, so that didn't really respond to anything, I'll move to strike that.
But my question was in the memory section of that document, does that refresh what your view was of the laser-cut mesh whenever this meeting occurred?
A. I don't recall this meeting in detail. This is, if someone would have tested on me, I would have failed that test.
MR. FREESE: I think that's all I got. I've got a lot more, but that's all for today.
(Witness was excused at 5:10 p.m.)

STATE OF FLORIDA,)
COUNTY OF PALM BEACH.)

I, the undersigned authority, certify that JAIME SEPULVEDA, M.D., personally appeared before me on April 8, 2016, and was duly sworn.

WITNESS my hand and official seal this 11th day of April, 2016.

_____

Dorothy Linda Minor, RPR

DOROTHY LINDA MINOR
MY COMMISSION # EE 187711
EXPIRES: August 8, 2016
Bonded Thru Budget Notary Services

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THE STATE OF FLORIDA,)
COUNTY OF PALM BEACH.)

I, Dorothy Linda Minor, Registered Professional Reporter, certify that I was authorized to and did stenographically report the deposition of JAIME SEPULVEDA, M.D.; that a review of the transcript was not requested; and that pages 7 through 328, inclusive, are a true and complete record of my stenographic notes.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorneys or counsel connected with the action, nor am I financially interested in the action.

DATED this 11th day of April, 2016.

____
Dorothy Linda Minor, RPR

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ERRATA

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ACKNOWLEDGMENT OF DEPONENT

I, JAIME SEPULVEDA, M.D., do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
JAIME SEPULVEDA, M.D. DATE

Subscribed and sworn
to before me this
_____ day of ______________, 20__.
My commission expires: __________
____
Notary Public

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